

HELUS PHARMA INC.

(formerly Cybin Inc.)

Management's Discussion and Analysis
of Financial Condition and Operating Performance

For the three and six months ended September 30, 2026

Date: November 12, 2026

HELUS PHARMA INC.

MANAGEMENT'S DISCUSSION AND ANALYSIS

This Management's Discussion and Analysis ("**MD&A**") has been prepared by management of Helus Pharma Inc., formerly known as Cybin Inc. ("**Helus Pharma**" or the "**Company**") and should be read in conjunction with Helus Pharma's unaudited condensed interim consolidated financial statements and notes for the three and six months ended September 30, 2026 (the "**Financial Statements**"). This MD&A does not address all of the changes to the Company and its business, such changes are addressed in the Company's most recently filed annual information form (the "**AIF**") on SEDAR+. The Financial Statements have been prepared using IFRS Accounting Standards ("**IFRS**") as issued by the International Accounting Standards Board.

This MD&A is dated November 12, 2026, for the period ended September 30, 2026, unless otherwise indicated. Effective April 1, 2025, the Company changed its presentation currency from the Canadian Dollar ("**CAD**" or "**C$**") to the United States dollar ("**$**" or "**USD**" or "**U.S. Dollars**") to better reflect the Company's operations, align with the currency in which the majority of cash based expenses are denominated, and improve comparability of its financial results with other publicly traded businesses in the industry. All dollar amounts are expressed in thousands, except share, per share and per unit amounts, or unless otherwise indicated. All amounts in the MD&A are presented in USD unless otherwise indicated. The Financial Statements may be viewed on the Company's SEDAR+ profile at www.sedarplus.ca.

FORWARD-LOOKING STATEMENTS

Certain statements, other than statements of historical fact, contained in this MD&A constitute "forward-looking information" and "forward-looking statements". These include without limitation, statements regarding future financial position, business strategy, budgets, research and development and plans and objectives of management for future operations. Such statements can, in some cases, be identified by the use of forward-looking terminology such as "expect," "likely", "may," "will," "should," "intend," or "anticipate," "potential," "proposed," "estimate" and other similar words, including negative and grammatical variations thereof, or statements that certain events or conditions "may" or "will" happen, or by discussions of strategy. The forward-looking statements included in this MD&A are made only as of the date of this MD&A and the Company assumes no obligation to update or revise them to reflect subsequent information, events or circumstances or otherwise, except as required by applicable securities laws.

Forward-looking statements in this MD&A are not guarantees of future performance and involve assumptions, risks, uncertainties, and other important factors that are difficult to predict. Therefore, actual results may differ materially from what is expressed, implied or forecasted in such forward-looking statements. Management provides forward-looking statements because it believes they provide useful information to readers when considering their investment objectives and cautions readers that the information may not be appropriate for other purposes.

Some of the risks which could affect future results and could cause results to differ materially from those expressed in the forward-looking statements contained herein include:

- limited operating history;
- achieving publicly announced milestones;
- speculative nature of investment risk;
- early stage of the industry and product development;
- dependence on the HLP003 Program;
- data may be negative or may change;
- regulatory risks and uncertainties;
- risks of operating in Australia and European countries;
- “foreign private issuer” status under U.S. Securities Laws;
- home country corporate governance practices;
- the Company may lose “foreign private issuer” status in the future;
- plans for growth;
- limited products;
- limited marketing and sales capabilities;
- no assurance of commercial success;
- no profits or significant revenues;
- reliance on third parties for clinical development activities;
- risks related to third party relationships;
- reliance on contract manufacturers;
- safety and efficacy of products;
- clinical testing and commercializing products;
- completion of clinical trials;
- commercial grade product manufacturing;
- nature of regulatory approvals;
- market access and acceptance;
- unfavorable publicity or consumer perception;
- social media;
- biotechnology and pharmaceutical market competition;
- reliance on key executives and scientists;
- employee misconduct;
- business expansion and growth;
- negative results of external clinical trials or studies;
- product liability;
- enforcing contracts;
- product and material recalls;
- distribution and supply chain interruption;
- difficulty to forecast;
- promoting the brand;
- product viability;
- success of quality control systems;
- reliance on key inputs;
- liability arising from fraudulent or illegal activity;
- operating risk and insurance coverage;
- costs of operating as public company;
- management of growth;

- conflicts of interest;
- foreign operations;
- exchange rate fluctuations;
- cybersecurity and privacy risk;
- risks related to artificial intelligence;
- environmental regulation and risks;
- legalization of scheduled serotonergic agonists;
- forward-looking statements may prove to be inaccurate;
- effects of inflation;
- disruptions at the FDA and other regulatory authorities could delay the review of the Company's regulatory submissions;
- tariffs, trade restrictions and drug pricing initiatives could adversely affect the Company;
- political and economic conditions;
- litigation risk;
- application and interpretation of tax laws;
- enforcement of civil liabilities;
- pandemics, epidemics and other health risks;

Risks Related to Intellectual Property:

- trademark protection;
- trade secrets, confidential information and know-how protection;
- patent protection;
- patent litigation;
- protection of intellectual property;
- third-party licenses;

Financial and Accounting Risks:

- substantial number of authorized but unissued Common Shares (as defined herein);
- dilution;
- negative cash flow from operating activities;
- additional capital requirements;
- lack of significant product revenue;
- estimates or judgments relating to critical accounting policies;
- inadequate internal controls;

Risks Related to the Common Shares:

- market for the Common Shares;
- significant sales of the Common Shares;
- volatile market price for the Common Shares;
- the Company expects to be a “passive foreign investment company”;
- tax issues; and
- no dividends.

Although the forward-looking statements contained in this MD&A are based upon what management currently believes to be reasonable assumptions, the Company cannot assure prospective investors that actual results, performance or achievements will be consistent with these forward-looking statements. In particular, the Company has made assumptions regarding, among other things:

- substantial fluctuation of losses from quarter to quarter and year to year due to numerous external risk factors, and anticipation that the Company will continue to incur significant losses in the future;
- uncertainty as to the Company's ability to raise additional funding to support operations;
- the Company's ability to access additional funding;
- the fluctuation of foreign exchange rates;
- the risks associated with pandemics;
- the risks associated with the development of the Company's product candidates which are at early stages of development;
- reliance upon industry publications as the Company's primary sources for third-party industry data and forecasts;
- reliance on third parties to plan, conduct and monitor the Company's preclinical studies and clinical trials;
- reliance on third party contract manufacturers to deliver quality clinical and preclinical materials;
- the Company's product candidates may fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or may not otherwise produce positive results;
- risks related to filing investigational new drug applications to commence clinical trials and to continue clinical trials if approved;
- the risks of delays and inability to complete clinical trials due to difficulties enrolling patients;
- competition from other biotechnology and pharmaceutical companies;
- the Company's reliance on the capabilities and experience of the Company's key executives and scientists and the resulting loss of any of these individuals;
- the Company's ability to fully realize the benefits of acquisitions;
- the Company's ability to adequately protect the Company's intellectual property and trade secrets;
- the risk of patent-related or other litigation; and
- the risk of unforeseen changes to the laws or regulations in the United States (the "**United States**" or the "**U.S.**"), the United Kingdom (the "**United Kingdom**" or the "**UK**"), Canada, the Netherlands, Ireland, Poland, Greece, Australia, and other jurisdictions in which the Company operates.

In particular, drug development involves long lead times, is very expensive and involves many variables of uncertainty. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to the Company. Every patient treated in future studies can change those assumptions either positively (for example, to indicate a faster timeline to new drug applications and other approvals) or negatively (for example, to indicate a slower timeline to new drug applications and other approvals). This MD&A contains certain forward-looking statements regarding anticipated or possible drug development timelines. Such statements are informed by, among other things, regulatory guidelines for developing a drug with safety studies,

proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date.

In addition to the factors set out above and those identified in this MD&A under "*Risk Factors*", other factors not currently viewed by the Company as material could cause actual results to differ materially from those described in the forward-looking statements. Although Helus Pharma has attempted to identify important risks and factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors and risks that cause actions, events or results not to be anticipated, estimated or intended. Accordingly, readers should not place any undue reliance on forward-looking statements.

OVERVIEW

The Company is a clinical-stage pharmaceutical company committed to improving the treatment landscape in mental health through the development and commercialization of novel serotonergic agonists ("**NSAs**"). Serotonergic agonists broadly refer to compounds that activate serotonin receptors and include a wide range of approved and investigational drugs with varying selectivity and mechanisms of action. NSAs are a proprietary subset of serotonergic agonists that are synthetically engineered to selectively activate specific serotonin receptor subtypes and signaling pathways, with the aim of achieving differentiated and more precise therapeutic effects.

The Company was incorporated under the laws of the Province of British Columbia and continued under the laws of the Province of Ontario as part of its November 5, 2020 reverse takeover transaction. Its wholly owned subsidiary, Helus Pharma Corp. (formerly Cybin Corp.) was incorporated under the laws of the Province of Ontario. Prior to November 5, 2020, the Company's operations were conducted through Helus Pharma Corp. (formerly Cybin Corp.).

On July 8, 2021, the Company announced the expansion of its European operations and research activities, including the transfer of its intellectual property assets to its wholly owned Irish subsidiary, Cybin IRL Limited ("**Cybin Ireland**"). On September 1, 2025, the Company incorporated Helus International Limited (formerly Cybin International Limited), a wholly owned subsidiary of Helus Pharma Corp.

On September 19, 2024, the Company consolidated its outstanding common shares (the "**Common Shares**") on the basis of one new Common Share for every 38 existing Common Shares (the "**Consolidation**"). As a result, all figures related to shares, warrants, options and earnings per share presented in this MD&A have been restated retrospectively for all periods to reflect the Consolidation.

On January 5, 2026, the Company transferred its U.S. stock exchange listing from NYSE American LLC stock exchange ("**NYSE American**") (previous ticker: CYBN) to the Nasdaq Global Market ("**Nasdaq**") under the ticker symbol "HELP". The Company continues to be listed on Cboe Canada Inc. ("**Cboe Canada**") under the same "HELP" ticker symbol. Concurrent with the commencement of trading on Nasdaq, the Company announced it will be doing business as Helus Pharma and started to operate under the registered business name "Helus Pharma". The Company's shareholders approved a legal name change to Helus Pharma Inc. at the annual and special meeting of shareholders held on

September 22, 2026, and the name change became effective on October 1, 2026. In addition, the following subsidiaries changed their legal names:

Prior Name	New Name	Effective Date
Cybin US Holdings Inc.	Helus US Inc.	January 2, 2026
Cybin Corp.	Helus Pharma Corp.	January 5, 2026
Cybin International Limited	Helus International Limited	January 6, 2026

Please refer to "*General Development of the Business*" in the AIF for additional information on the background and operational highlights of Helus Pharma. The AIF may be viewed under the Company's SEDAR+ profile at www.sedarplus.ca.

BUSINESS OVERVIEW

The Company is a clinical-stage pharmaceutical company committed to improving the treatment landscape in mental health conditions through the development and commercialization of NSAs.[1]

Helus Pharma's research and development work leverages the Company's core competencies in preclinical innovation and clinical development. This strategy focuses on developing the Company's platform technology to develop NSAs, the progression of clinical development programs studying certain of these NSAs, including HLP003 (previously referred to as CYB003), a deuterated psilocin molecule ("**HLP003**"), HLP004 (previously referred to as CYB004), a deuterated version of DMT ("**HLP004**"), HLP005 (previously referred to as CYB005), phenethylamine and tryptamine derivatives (together "**HLP005**"), and an expansive list of preclinical molecules to facilitate future drug development opportunities.

On October 23, 2023, the Company completed the acquisition of Small Pharma Inc. ("**Small Pharma**") by way of a statutory plan of arrangement under the provisions of the *Business Corporations Act* (British Columbia) (the "**Arrangement**"), pursuant to which Small Pharma became a wholly-owned subsidiary of Helus Pharma. On April 1, 2024, pursuant to the provisions of the *Business Corporations Act* (Ontario) (the "**OBCA**"**)**, Small Pharma completed a horizontal amalgamation with Helus Pharma Corp., with Helus Pharma Corp. being the resulting entity. As a result of this amalgamation, Cybin UK Ltd. T/A Helus is now a wholly-owned subsidiary of Helus Pharma Corp. Small Pharma was a biotechnology company focused on developing short-duration therapies for the treatment of mental health conditions. Small Pharma initiated programs across its "First-generation" and "Second-generation" serotonergic agonist portfolio. First-generation serotonergic agonists refer to serotonergic agonists found in nature or previously studied. Second-generation serotonergic agonists refer to NSAs, which are often first-generation serotonergic agonists that have been chemically modified with the aim to optimize their therapeutic benefit.

[1] This is a forward-looking statement that involves material assumptions by the Company. Drug development involves long lead times, is very expensive and involves many variables of uncertainty. Anticipated timelines regarding drug development and recruitment of patients for participation in clinical trials are dependent on various factors and are based on reasonable assumptions informed by current knowledge and information available to the Company. Such statements are informed by, among other things, eligibility and exclusion criteria for the trial, design of the clinical trial, competition with other companies for clinical sites or patients, perceived risks and benefits of the prescription drug product candidate, the number, availability, location and accessibility of clinical trial sites, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date.

Advancement of Mental Healthcare

The Company is conducting research and development of next-generation therapeutics that aim to address unmet needs in the treatment of mental health conditions. This comprehensive development work is predicated on structural modifications of known tryptamine and phenethylamine derivatives to improve their pharmacokinetic properties while maintaining their respective pharmacology.

Across its extensive research and development programs, Helus Pharma is evaluating a wide array of novel, synthetic active pharmaceutical ingredients ("**API**") intended to be delivered through innovative drug delivery systems including via intravenous ("**IV**"), intramuscular, or subcutaneous administration.[2]

The Company intends to apply for regulatory approval for therapies targeting indications such as major depressive disorder ("**MDD**"), alcohol use disorder ("**AUD**"), generalized anxiety disorder ("**GAD**") and potentially other various mental health conditions.[3] The Company is also developing compounds that may have the potential to address neuroinflammation, central nervous system ("**CNS**") disorders, and psychiatric disorders.[4]

Stage of Development

Like most life sciences and pharmaceutical companies, the Company's business is focused on research and development and any future revenue will be dependent on a number of factors, including the outcome of the Company's clinical trials and the receipt of all necessary regulatory approvals.

Prescription drugs are classified and regulated under the federal *Food and Drugs Act* (Canada) (the "**Canadian FDA**"). Labeling, marketing and selling of any prescription drug must comply with the Canadian FDA, including by ensuring that the Company's products are not packaged or marketed in a manner that is misleading or deceptive to a consumer.

In the United States, foods, drugs and dietary supplements are subject to extensive regulation. The *Federal Food, Drug, and Cosmetic Act* (the "**FFDCA**") and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacturing, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. The Company must ensure that all promotion and marketing, distribution, and labeling of any pharmaceutical products comply with the U.S. regulations, including the FFDCA and the U.S. Food and Drug Administration (the "**FDA**").

The Company holds a Schedule I manufacturing license from the U.S. Drug Enforcement Administration ("**DEA**") for its research lab in the Boston area. The license allows the Company to further become a hub for innovation and drug discovery. With the DEA license, the Company has

[2] See footnote 1.
[3] See footnote 1.
[4] See footnote 1.

expanded its internal R&D capabilities to support innovative drug discovery and delivery involving Schedule I compounds.

On March 13, 2024, the Company announced that it had been granted Breakthrough Therapy Designation (the "**BTD**") by the FDA in respect of HLP003. The BTD provides an expedited review pathway, as well as increased access to FDA guidance on trial design, which has the potential to significantly reduce drug development timelines. The designation includes all "fast track" program features, as well as more intensive FDA guidance and discussion of the HLP003 development program, including planned clinical trials and plans for expediting the manufacturing development strategy.

Non-Revenue Generating Projects[5]

The Company currently has three significant projects, which have not yet generated revenue:

1. HLP003 Program[6]
2. HLP004 Program[7]
3. HLP005 Program[8]

The Company has been investigating the development of NSAs with the aim of creating clinical development candidates, utilizing (i) the chemical modification of known serotonergic agonists through the selective substitution of hydrogen atoms with deuterium (i.e. deuteration); and (ii) the combination of such deuterated tryptamine derivative molecules with selected drug delivery methods, including but not limited to oral, inhalation methods, IV and intramuscular delivery.

The Company has developed EMBARK, a psychological support model that integrates leading clinical approaches to promote supportive healing with pharmacological interventions for neuropsychiatry. EMBARK's six clinical domains (**E**xistential-Spiritual, **M**indfulness, **B**ody Aware, **A**ffective-Cognitive, **R**elational, **K**eeping Momentum) represent the broad spectrum of ways in which therapeutic benefits may arise in treatment and the equally broad training needed to prepare therapists to support them all. The Company launched its EMBARK training program in June 2021, which prepares facilitators to work within all of these domains, while inviting facilitators to bring in their own therapeutic training and expertise in a flexible, yet structured way. The EMBARK curriculum additionally emphasizes trauma-informed, culturally competent, and ethically rigorous care. On April 12, 2023, the Company announced the launch of EMBARK Open Access ("**EMBARK OA**"), a free online foundational training course for facilitation. EMBARK Open Access is the first and only free massive open online course that offers foundational facilitation training for healthcare professionals and people interested in offering psychological support. On July 12, 2023, the Company announced that it has commenced the development of a streamlined, scalable version of its EMBARK Training Program, known as EMBARK^{CT}, which is designed for individuals with existing knowledge, skills, and experience in facilitation. The EMBARK^{CT} training program is expected to enable the Company to effectively screen, qualify, and train facilitators on a multi-site, international level, to provide

[5] All quarter references in this section are based on calendar year-end.
[6] Formerly named the Deuterated Psilocin Program (CYB003)
[7] Formerly named the Deuterated Dimethyltryptamine Program (CYB004).
[8] Formerly named the Phenethylamine and Tryptamine Derivatives Program (CYB005).

support and in-person monitoring for study participants receiving the Company's investigational therapeutics in larger pivotal trials.

About the HLP003 Program

The Company's lead program, HLP003, is an orally delivered deuterated NSA that has been granted FDA BTD for the potential adjunctive treatment of MDD. HLP003 aims to address the limitations of first-generation serotonergic agonists, including side effects, scalability and accessibility of treatment.

The Company completed its HLP003 Investigational New Drug ("**IND**")-enabling preclinical studies and Chemistry, Manufacturing and Control ("**CMC**"**)** development, including the production of clinical materials required for clinical trials, in the second quarter of calendar 2022. In the same period, the Company submitted an IND application to the FDA and received a "may proceed letter" and IND application clearance from the FDA as well as Institutional Review Board (the "**IRB**") approval in the U.S. to commence its first-in-human Phase 1/2a study of HLP003 in participants with moderate to severe MDD.

About the Completed HLP003 Phase 1/2a Clinical Trial

The Phase 1/2a trial was a randomized, double-blind, placebo-controlled study evaluating HLP003 in participants with moderate to severe MDD and in healthy volunteers. Per a protocol amendment to the initial Phase 1/2a study design that was announced on February 28, 2023, the study introduced healthy volunteers for the lower (sub-therapeutic) dose cohorts and added a bioequivalence cohort to facilitate the transition to pivotal studies. Healthy volunteers received two administrations (placebo/active and active/active) one week apart, and measures of pharmacological effect were assessed after each dose. Participants with MDD received two administrations (placebo/active and active/active) three weeks apart and response/remission were assessed three weeks after each dose. MDD participants in the trial that were being treated with antidepressants were allowed to remain on their antidepressant medication.

The study investigated the safety, tolerability, pharmacokinetics ("**PK**") and pharmacodynamics ("**PD**"), and pharmacological effect of ascending oral doses of HLP003. In participants with MDD, the trial evaluated rapid onset of antidepressant effect on the day of dosing, using the Montgomery-Asberg Depression Rating Scale ("**MADRS**"), and evaluated the incremental benefit of a second dose of HLP003 when administered at Week 3. The study included an optional period of assessment to evaluate the durability of treatment effect out to 12 months.

On November 30, 2023, the Company announced positive Phase 2a topline results for HLP003, showing rapid and robust improvements in symptoms of depression after single doses of HLP003, with an average 14.1 point difference in MADRS score reduction between HLP003 and placebo which was statistically significant at 3 weeks ($p<0.0001$). The study also demonstrated a clear incremental benefit of a second dose, with a further 5.8 point improvement on the MADRS total score with a second dose of HLP003 (12 mg) at 6 weeks, and 79% of patients were in remission from depression at 6 weeks after two doses of HLP003 (12 mg). HLP003 exhibited a favorable safety and tolerability profile with no treatment-related serious adverse events at 12 mg and 16 mg doses.

On March 13, 2024, the Company reported positive four-month durability data from the Phase 2a study of HLP003 in MDD. These results showed robust, sustained and statistically significant improvements in depression symptoms at four months with two doses of HLP003 (12 mg or 16 mg):

- Average mean reduction from baseline in the MADRS total score across 2 cohorts was approximately 22 points from baseline in both dosing cohorts.
- 60% of patients on 12 mg and 75% on 16 mg were in remission from depression following 2 doses (MADRS score ≤ = 10).

On November 18, 2024, the Company reported positive Phase 2 data for HLP003, demonstrating 12-month efficacy in treating MDD. At 12 months after two 16 mg doses, 100% of participants were responsive to treatment and 71% of participants were in remission. The mean change from baseline in MADRS was approximately -23 points at 12 months after two 16 mg doses. HLP003 demonstrated a favorable safety and tolerability profile. No new adverse events were reported in the 12-month follow up, including no reports of suicidality.

About the Phase 3 PARADIGM Pivotal Program

On November 13, 2024, the Company announced that it had initiated PARADIGM, a multinational pivotal Phase 3 program evaluating HLP003 for the potential adjunctive treatment of MDD.

The Company's Phase 3 program comprises three pivotal efficacy studies as outlined below. Dosing has completed in APPROACH, the first pivotal study, the EMBRACE study is ongoing, and patient rollover is ongoing into EXTEND (as defined below).

Pivotal study 1: APPROACH ™ (A Phase 3, Placebo-Controlled, Randomized, Double-Blind Trial of Oral Doses of HLP003 to Assess Combined Safety and Efficacy in Humans with Major Depressive Disorder)("**APPROACH**").

- Participants (N=223) were randomized 1:1 to receive either 16 mg of HLP003 or inactive placebo. Each study arm evaluated a two-dose regimen, with doses administered three weeks apart. The study enrolled patients suffering from moderate to severe MDD (MADRS≥24) who were on a stable dose of antidepressant medication but were responding inadequately.
- The primary endpoint was a change in depressive symptoms as measured by change in MADRS from baseline at six weeks after the first dose.

On July 21, 2026, the Company announced that it had completed enrollment of 223 participants in APPROACH across clinical sites in the U.S.

Pivotal study 2: EMBRACE™ (An Efficacy and Safety, Phase 3, Multi-center, Double-Blind, Randomized Controlled Study Comparing 2 Active Doses of HLP003 and Placebo in Eligible Participants With Major Depressive Disorder) ("**EMBRACE**").

- Participants (n=330) are randomized 1:1:1 to receive 16 mg of HLP003 (n=110), 8 mg of HLP003 (n=110), or inactive placebo (n=110). Each arm will evaluate a two-dose regimen, with doses administered three weeks apart. The study is enrolling patients suffering from

moderate to severe MDD (MADRS≥24) who are on a stable dose of antidepressant medication but are responding inadequately.
- The primary endpoint is change in depressive symptoms as measured by change in MADRS from baseline at six weeks after the first dose.

EMBRACE is expected to enroll at approximately 70 clinical sites.

Pivotal study 3: ("**EXTEND**"**)** (A Phase 3 Long-Term Extension Study with Optional Additional Doses of HLP003 to Assess the Safety and Long-term Efficacy in Participants With Major Depressive Disorder).

- Participants from APPROACH and EMBRACE may roll over into EXTEND (up to n=550) after the completion of the 12-week, double-blind, placebo-controlled treatment periods. During EXTEND, all participants who did not respond to treatment in the APPROACH and EMBRACE studies or who relapse during the EXTEND study will be eligible to receive an additional two doses of HLP003 (16 mg) administered three weeks apart. Participants who do not respond to these two doses or relapse again will be eligible to receive an additional single 16 mg dose of HLP003.

Across all three studies, raters are remote, independent, and blinded with no information on the dose received or the participant's dosing experience. Effects during the dosing session are firewalled to ensure that the study team stays blinded.

The Company spent approximately $43,182 on the HLP003 Program during the six months ended September 30, 2026.

As the Company continues to progress through the HLP003 Program, additional milestones related to its clinical development have been identified. The Company intends to:

- Provide topline efficacy data readout from the first Phase 3 study, APPROACH, in Q4 2026.[9]

The Company expects to spend approximately $51,105[10] to provide topline efficacy data readout from the first Phase 3 study, APPROACH, in Q4 2026. Of this amount, approximately $22,005 was spent during the six months ended September 30, 2026, and approximately $26,171 was spent in prior fiscal years, resulting in an approximate remaining spend as of September 30, 2026, of $2,929 by the milestone completion in Q4 2026.[11]

[9] There is no assurance that this timeline will be met or that the program will advance to clinical trials, at all. Drug development involves long lead times, is very expensive and involves many variables of uncertainty. Anticipated timelines regarding drug development and recruitment of patients for participation in clinical trials are dependent on various factors and are based on reasonable assumptions informed by current knowledge and information available to the Company. Such statements are informed by, among other things, eligibility and exclusion criteria for the trial, design of the clinical trial, competition with other companies for clinical sites or patients, perceived risks and benefits of the prescription drug product candidate, the number, availability, location and accessibility of clinical trial sites, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date. The Company is currently prioritizing the advancement of its HLP003 Program.

[10] See footnote 9.

[11] See footnote 9.

The Company intends to continue funding the HLP003 Program, and is targeting a potential FDA New Drug Application ("**NDA**") filing in 2028[12].

About the HLP004 Program

The Company's proprietary HLP004 Program is being developed as an intermittent treatment with the potential for less invasive, more convenient and patient-friendly dosing methods for the potential treatment of GAD. A single intramuscular ("**IM**") dose is expected to result in desired pharmacological effects lasting an average of 90 minutes.

Through its acquisition of a Phase 1 DMT study from Entheon Biomedical Corp. ("**Entheon**")[13], the Company obtained healthy volunteer clinical data on IV native (non-deuterated) N,N-dimethyltryptamine ("**DMT**"), from Part A of the HLP004-E study, which showed with a 90 minute infusion of DMT, a dose-proportional increase in exposure, dose-related increases in subjective pharmacological effects, and good tolerability, but not the breakthrough experiences it expected with the dose levels studied. Therefore, using data from Part A, the Company designed Part B and Part C of the HLP004-E study. In Part B, the Company explored a combination of intravenous bolus followed by an infusion and concluded that the rate at which drug concentrations reached a therapeutic window was crucial. The Company then, in Part C, evaluated HLP004, a deuterated form of DMT, in healthy volunteers, which showed robust and rapid-onset pharmacological effects at lower doses compared to native DMT. These results support the Company's rationale for deuteration.

Through its acquisition of Small Pharma, the Company obtained two additional DMT programs and their associated clinical data:

SPL026 (IV/IM native DMT): Phase 2a and Phase 1b studies in participants with MDD, including data from SPL026 administered in conjunction with selective serotonin reuptake inhibitors ("**SSRIs**"), demonstrated reductions in depression symptoms, durable response and a favorable safety profile. Exploratory analyses of these studies also suggested meaningful improvements in symptoms of anxiety, as measured by the State Trait Anxiety Inventory – Trait version ("**STAI-T**"), which formed the basis for selecting GAD as the indication for HLP004. In addition, a Phase 1 study of IM SPL026 showed that IM delivery of native DMT was well-tolerated, supporting IM administration as a patient-friendly dosing method.

SPL028 (IV/IM deuterated DMT): A Phase 1 study in healthy volunteers showed that IM dosing of deuterated DMT was well-tolerated and produced robust pharmacological effects of short duration, averaging approximately 90 minutes (ranging from approximately 55 to 120 minutes) in the majority of subjects, supporting IM administration as a viable dosing route for deuterated DMT and supporting IM dosing for HLP004.

[12] See footnote 9.

[13] On July 11, 2022, the Company completed the acquisition from Entheon of a Phase 1 DMT study conducted in the Netherlands, previously identified as EBRX-101 and now known as HLP004-E (the "Asset Acquisition"). In connection with the Asset Acquisition, Entheon assigned to the Company its rights under a master services agreement with Centre for Human Drug Research, an independent Netherlands-based institute specializing in early-stage clinical drug research.

By integrating the data from these seven completed clinical trials across three DMT molecules – HLP004 and SPL028 (each a deuterated DMT) and SPL026 (native DMT) – the Company was able to inform and optimize the design of the HLP004 Program. Specifically, the Company selected HLP004, its own deuterated DMT molecule, as its lead molecule, based on the results of its Phase 1 study of IV HLP004 as compared against the native IV DMT healthy volunteer data obtained from Entheon; IM administration as its dosing route, based on learnings from the IM studies of SPL028 and SPL026; and GAD as its indication was further supported by the anxiety signal observed in the SPL026 studies.

The Company is currently advancing HLP004, a deuterated version of DMT, for the potential treatment of GAD. DMT activates the serotonin 5-HT2A receptor, which is believed to mediate the potential therapeutic effects of DMT. Building on the combined datasets described herein, the Company initiated a Phase 2 study of IM HLP004 in participants with moderate to severe GAD, which the Company believes has the potential to offer more convenient and patient-friendly dosing.

About the Phase 1 HLP004-E Study

The Phase 1 trial was a three-part study evaluating the safety, pharmacokinetics, and pharmacodynamics of escalating doses of DMT and HLP004 in healthy volunteers. The three-part study design was established in a protocol amendment to the initial study design, allowing the Company to commence first-in-human dosing of HLP004 sooner than initially planned. The study provided essential safety and dosing optimization data informing the clinical path forward for HLP004. The HLP004-E study was conducted at the Centre for Human Drug Research in the Netherlands and is one of the largest Phase 1 DMT clinical trials to date.

The Company was able to rely upon completed preclinical data to gain regulatory authorization to add HLP004 to the HLP004-E DMT Study. The Company also announced confirmatory data from Part A, the single ascending dose portion of the HLP004-E study, which assessed a continuous IV DMT infusion. The Part A data showed a dose-proportional increase in exposure and dose-related increase in behavioral measures of subjective pharmacological effects with IV DMT. IV DMT was also well-tolerated with no safety issues and no serious adverse events within the dose range evaluated.

On January 8, 2024, the Company announced positive topline results from its Phase 1 studies of its proprietary molecules, HLP004 and SPL028.

- The Phase 1 HLP004 study results showed that IV HLP004 demonstrated robust and rapid-onset pharmacological effects at lower doses compared to the non-deuterated molecule. These pharmacological effects were rapid in onset when administered as an IV bolus over five minutes and persisted for about 40 minutes after the bolus without the need for an extended infusion.
- The Phase 1 SPL028 study identified an IM dose of SPL028 that resulted in desired pharmacological effects, with a total duration ranging from 55 to 120 minutes.
- Both HLP004 (IV) and SPL028 (IM and IV) were well-tolerated with no serious adverse events, and the majority of adverse events were mild to moderate and self-limiting.

On March 15, 2024, the Company announced that it had initiated a Phase 2 study of IM HLP004 in participants with moderate to severe GAD.

About the Completed Phase 2 HLP004 Study in GAD

The HLP004-002 Phase 2 study was a randomized, double-blind study which evaluated the safety and efficacy of HLP004 in participants with moderate to severe GAD (GAD-7 score ≥10), with concomitant antidepressant/anxiolytic treatment and co-morbid depression allowed. The study recruited 36 participants, who were randomized in a double-blind manner, into two groups. The first group received two IM doses of HLP004, three weeks apart, while the second group received two low-dose control administrations of sub-therapeutic doses of HLP004. The primary endpoint was a change in the Hamilton Anxiety Rating Scale score from baseline at six weeks following the first dose with an additional efficacy assessment twelve weeks following the first dose. Other endpoints included the HAM-D (Hamilton Depression Rating Scale), safety assessments, MEQ30 (mystical experience questionnaire) and EQ-5D-5L (quality of life assessment). Participants were eligible to enroll into an optional follow up for up to a year.

On September 8, 2025, the Company announced that it had completed enrollment in the Phase 2 study of HLP004 in GAD.

On March 5, 2026, the Company announced topline results from its Phase 2 study of HLP004 in GAD. Key findings included:

- Clinically meaningful efficacy: Patients that received 20mg HLP004 adjunctive to Standard of Care therapy achieved mean reduction of 10.4-points ($p<0.0001$) in the HAM-A from baseline at six weeks.
- Efficacy in difficult to treat population: Study population consisted of moderate-to-severe patients who remained symptomatic despite ongoing antidepressant or anxiolytic therapy.
- Durable remission and robust response over time:
    - At six months, the pooled study population showed 67% responders and 39% remitters.
    - Participants randomized to both 20mg and 2mg dosing arms experienced meaningful subjective effects and showed clinically significant improvements over baseline when administered with Standard of Care, with 59% meeting the criteria for response and 32% for remission in the 20mg arm and a 30% responder and remitter rate in the 2mg arm at week 6.
- Well tolerated: Favorable tolerability profile with no drug-related serious adverse events or suicidality-related safety signals.

The HLP004-002 Phase 2 study demonstrated evidence that supported the selection of 30 mg as the appropriate dose for further development in a monotherapy GAD study.

The Company spent approximately $1,837 on the HLP004 Program during the six months ended September 30, 2026.

As the Company continues to progress its HLP004 Program, additional milestones related to its clinical development have been identified. The Company intends to:

- Initiate a Phase 2 monotherapy study by the end of Q1 2027[14]

The Company spent approximately $56[15] to complete the design of the next HLP004 study during the six months ended September 30, 2026.

The Company expects to spend approximately $6,329 to initiate a Phase 2 monotherapy study by the end of Q1 2027.[16] No amounts were spent toward the achievement of this milestone during the six months ended September 30, 2026. The Company intends to continue funding the HLP004 Program.

About the HLP005 Program

The Company's Phenethylamine and Tryptamine Derivatives Program (HLP005) is focused on the development of therapeutic phenethylamine and tryptamine derivatives. In Q2 2025, the program, which historically focused on phenethylamine derivatives, was expanded to include tryptamine derivatives. Studies that have been conducted with compounds of a similar chemical structure have demonstrated potential for therapeutic use. The HLP005 program builds upon the current understanding of the mechanisms of action of NSAs and aims to identify key polypharmacological combinations capable of mediating therapeutic effects for target indications. Helus Pharma's proprietary approach to phenethylamines and tryptamines modification with novel chemistry, proprietary formulations and directed delivery systems has yielded a number of novel, IP-protected leads with diverse pharmacology. Several compounds are now being further studied both in vitro and in vivo for selection of the best development candidates based on qualitative assessment of acute pharmacological effects, mechanistic studies, pharmacokinetics and efficacy and safety of chronic dosing. The Company is investigating the efficacy and durability of the lead compounds to determine their potential for the treatment of a range of psychiatric and neurological conditions.[17]

The Company spent approximately $342 on its HLP005 Program during the six months ended September 30, 2026.

The Company anticipates that its HLP005 Program will deliver a drug development candidate during the second half of 2027.

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[14] See footnote 9.

[15] The Company had previously estimated total spend associated with this milestone of approximately $150. Actual spend was lower than initially estimated primarily due to a greater proportion of work being performed internally rather than outsourced. See also footnote 9.

[16] See footnote 9.

[17] This statement is based on the following material factors and assumptions: (a) the Company assumes it will enter into a contract with a licensed third-party vendor to undertake extensive preclinical characterization of target molecules on the Company's behalf; (b) the Company anticipates to complete a number of animal models and the completion of ADME profiles; (c) the Company assumes to enter into third party agreements in order to complete a range of additional preclinical programs including but not limited to dose-ranging studies in multiple animal species, toxicity studies in multiple animal species, genotoxicity studies, teratogenicity studies, along with neuropharmacological, pulmonary, and cardiovascular profiling before the final selection of drug candidates for entry into human trials; and (d) obtain an IND and/or a CTA to enter into clinical trials. As of the date hereof, it has not yet completed the aforementioned items. Such statements are informed by, among other things, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date.

The Company expects to spend approximately $2,535[18] to deliver a drug development candidate by the end of the second half of 2027.[19] Of this amount, approximately $342 was spent during the six months ended September 30, 2026 and approximately $1,483 was spent in prior fiscal years, resulting in an approximate remaining spend as of September 30, 2026, of $710 by the milestone completion in the second half of 2027[20]. The Company intends to continue funding the HLP005 program.

Relationships with Third Parties

The Company's research and development of its pharmaceutical products is conducted by way of licensed partners. The Company also intends to sponsor clinical and other studies at various clinical trial sites.

Mindset Pharma Inc.

On September 27, 2022, the Company entered into an agreement, as amended, with Mindset Pharma Inc. ("**Mindset**") to acquire an exclusive license to an extensive targeted class of tryptamine-based molecules. The agreement includes an initial license fee payment by Helus Pharma to Mindset of $500 as well as additional clinical development milestone payments of up to $9,500, with the first milestone payment, in the amount of $500, payable upon completion of a Phase 1 clinical trial. At the sole discretion of Helus Pharma, the milestones may be paid in cash or in Common Shares, or a combination thereof, subject to the approval of Cboe Canada. There is no assurance that the aforementioned milestones will be met. The agreement also contemplates a sales royalty of approximately 2% for all commercialized licensed products within the scope of the agreement, which is customary for drug licensing agreements of this nature.

Worldwide Clinical Trials

On July 26, 2023, the Company announced that it has partnered with Worldwide Clinical Trials, a global, full-service contract research organization with deep expertise managing clinical trials for mental health conditions, including MDD.

Osmind

On April 21, 2025, the Company announced a strategic partnership with Osmind, a leading service provider advancing psychiatry through technology, services, and real-world evidence to bring innovative mental health treatments to patients in need. Through this partnership, the Company will leverage Osmind's 800-clinic network, point-of-care software, and real-world data to support the commercial preparation for its clinical-stage pipeline.

Thermo Fisher Scientific

On May 15, 2025, the Company announced that it has engaged Thermo Fisher Scientific to provide U.S.-based manufacturing for the HLP003 Program. The production of both drug substance and drug product will be performed at Thermo Fisher's U.S. pharma services manufacturing sites. The

[18] See footnote 9.
[19] See footnote 9.
[20] See footnote 9.

Company is working with Thermo Fisher's pharma services sites in Florence, South Carolina, for Phase 3 clinical supply and future commercialization, and Cincinnati, Ohio, for Phase 3 capsule production and commercialization.

Other Third-Party Partners

The Company has established contractual sources of synthetic GMP and non-GMP raw materials to support its development operations through licensed third-party suppliers. Such raw materials are expected to be, in general, readily available and in adequate supply to meet the Company's need for development quantities, or custom manufactured on the Company's behalf.[21] The prices of research quantities of novel tryptamine compounds are generally higher than commercial supply prices at significantly larger scale and the Company, therefore, expects its supply prices to reduce over time. Development and production of the Company's proprietary novel compounds is performed under confidential contractual agreements.

The Company has conducted due diligence on each such third party, including but not limited to the review of necessary licences and the regulatory framework enacted in the jurisdiction of operation.

The allocation of capital towards the Company's ongoing projects and programs is largely dependent on the success, or difficulties encountered, in any particular portion of the process and therefore the time involved in completing it; in turn the time and costs associated with completing each step are highly dependent on the incremental results of each step and the results of other programs, and the Company's need to be flexible to rapidly reallocate capital to projects whose results show the greatest potential. As such, it is difficult for the Company to anticipate the timing and costs associated with taking the projects to their next planned stage, and the Company cannot make assurances that the foregoing estimates will prove to be accurate, as actual results and future events could differ materially from those anticipated. Accordingly, investors are cautioned not to put undue reliance on the foregoing estimates.

Moreover, identifying the timing and costs of such projects beyond their immediate next steps go to the core differentiating factors with respect to the Company and its competitors. The disclosure of prospective costs and timing other than as already disclosed by the Company would negatively impact shareholder value and undermine the Company's proprietary technology. In keeping with pharmaceutical industry practice, it is the Company's policy to disclose these details in conjunction with its financial statements, and to publicly disclose published patent applications, published scientific papers, scientific symposia and the attainment of key milestones only. In addition, the premature disclosure of proprietary data would have a material and adverse effect on the Company's patent and other intellectual property rights and could result in the breach of confidentiality obligations.

The estimated costs disclosed herein are subject to the risks, uncertainties, and other important factors disclosed in the "*Forward-Looking Statements*" and "*Risk Factors.*"

[21] At this time the Company has not entered into commercial supply agreements and has no control over price or conditions. The Company has assumed that it will be able to enter into commercial supply agreements at such a time when there will be sufficient competition in the market which will render prices reasonable.

There is no guarantee that the Company will meet its business objectives or milestones described above within the specific time periods, within the estimated costs or at all. The Company may, for sound business reasons, reallocate its time or capital resources, or both, differently than as described above.

The Company has negative cash flow from operating activities and has historically incurred net losses. To the extent that the Company has negative operating cash flows in future periods, it may need to deploy a portion of its existing working capital to fund such negative cash flows. The Company will be required to raise additional funds through the issuance of additional equity and/or equity-linked securities, through loan financing, or other means, such as through partnerships with other companies and research and development reimbursements. There is no assurance that additional capital or other types of financing will be available if needed or that these financings will be on terms at least as favorable to the Company as those previously obtained.

The expected use of net proceeds from the Company's previous financing activities represent the Company's current intentions based upon its present plans and business condition, which could change in the future as its plans and business conditions evolve. The amounts and timing of the actual use of the net proceeds will depend on multiple factors and there may be circumstances where, a reallocation of funds may be necessary in order for the Company to achieve its stated business objectives or because its business objectives have evolved. The Company anticipates that it will require additional funds in order to fulfill its expenditure requirements to meet existing and any new business objectives, and the Company expects to either issue additional securities or incur debt to do so.

Intellectual Property

The Company's intellectual property portfolio includes patents and patent applications, trademarks and trademark applications, copyrights, licensing agreements, and trade secrets. The following tables list issued patents and pending patent applications in the Company's patent portfolio, including patents and applications directed to the Company's HLP003, HLP004, and HLP005 programs, as well as other subject matter.

As of November 11, 2026, Helus Pharma has title to thirty granted US patents and one hundred and sixteen granted national (non-US) patents, including claims directed to compositions of matter and methods of use in support of its research and development and preclinical and clinical trial programs. Granted European patents are counted as a single granted patent (as opposed to multiple patents in each European territory in which the patent is in force). Certain of the Company's patent rights may be subject to out-license and option arrangements, which may limit Helus Pharma's ability to use or further out-license such patent rights.

Patent Number	Jurisdiction of Filing
11,242,318	United States
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11,746,088	United States
11,834,410	United States
11,958,807	United States
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7766623	Japan
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312785	Israel
11202254530T	Singapore
437252	Mexico
7915355	Japan
2024203974	Australia
297492	Israel
2021276656	Australia
74.422	Chile
793553	New Zealand
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7802769	Japan
2021327136	Australia
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2021328671	Australia
12751940	United States
12735386	United States
2022239825	Australia
2022277515	Australia
4340809	European Patent Office
40102138	Hong Kong
2022342266	Australia
2022381220	Australia
2023207801	Australia
2018311307	Australia
2020378647	Australia
2020381103	Australia
2021334933	Australia
2021204158	Australia
2020286709	Australia
2021284861	Australia
2021391581	Australia
1120220221983	Brazil
1120220245661	Brazil
3104072	Canada
3160337	Canada
3179161	Canada
3142290	Canada
3160334	Canada
3179335	Canada
ZL202080087091.0	China
ZL202080087092.5	China
ZL202180044031.5	China
ZL202180046463.X	China
ZL202080050439.9	China
ZL202180090269.1	China
046951	Eurasian Patent Office
048675	Eurasian Patent Office
049402	Eurasian Patent Office
049106	Eurasian Patent Office
3463323	European Patent Office

Patent Number	Jurisdiction of Filing
3687515	European Patent Office
3532457	European Patent Office
3826632	European Patent Office
3844147	European Patent Office
3873883	European Patent Office
3902541	European Patent Office
4031529	European Patent Office
4062910	European Patent Office
4138818	European Patent Office
4149460	European Patent Office
4275753	European Patent Office
40042383	Hong Kong
40035970	Hong Kong
40056359	Hong Kong
40060666	Hong Kong
40065709	Hong Kong
40064531	Hong Kong
40045846	Hong Kong
40060891	Hong Kong
40078818	Hong Kong
40089095	Hong Kong
40103232	Hong Kong
507114	India
528813	India
570120	India
592466	India
599786	India
292753	Israel
288617	Israel
298542	Israel
292754	Israel
298129	Israel
298541	Israel
7288154	Japan
7422474	Japan
7423131	Japan
7422473	Japan
7523474	Japan
7579888	Japan
7748437	Japan
7834754	Japan
ZL202180044031.5	Macao
ZL202080087092.5	Macao
ZL202180046463.X	Macao
ZL202080050439.9	Macao
ZL202180090269.1	Macao
404310	Mexico
411316	Mexico
412331	Mexico
415678	Mexico
788543	New Zealand
794833	New Zealand
793361	New Zealand

Patent Number	Jurisdiction of Filing
794813	New Zealand
783166	New Zealand
800961	New Zealand
811102	New Zealand
2589605	Republic of Korea
2636385	Republic of Korea
3030685	Republic of Korea
2023/01086	South Africa
2024/03906	South Africa
I891942	Taiwan
I860478	Taiwan
2585978	United Kingdom
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2592822	United Kingdom
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12,157,723	United States
12,251,371	United States
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In addition, as of November 11, 2026, Helus Pharma has title to four provisional patent applications, thirty six US non-provisional patent applications, two hundred and thirty six national (non-US) patent applications, and three Patent Cooperation Treaty ("**PCT**") applications, including claims directed to compositions of matter and methods of use in support of its research and development and preclinical and clinical trial programs.

Patent Application Number	Jurisdiction of Filing	Status
18/561,152	United States	Pending
18/576,487	United States	Pending
18/588,132	United States	Pending
18/688,125	United States	Pending
18/707,825	United States	Pending
18/720,922	United States	Pending
PCT/EP2024/067458	WIPO	Pending
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18/730,423	United States	Pending
18/825,122	United States	Pending

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18/850,356	United States	Pending
18/852,115	United States	Pending
18/867,231	United States	Pending
19/020,095	United States	Pending
19/106,551	United States	Pending
19/119,308	United States	Pending
19/170,327	United States	Pending
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19/488,218	United States	Pending
63/928,477	United States	Pending
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19/629,961	United States	Pending
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64/093,493	United States	Pending
19/752,805	United States	Pending
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19/889,866	United States	Pending
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832747	New Zealand	Pending
325449	Israel	Pending
3177454	Canada	Pending
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NC2026/0005091	Colombia	Pending
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3186357	Canada	Pending
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202380016531.7	China	Pending
23700949.3	European Patent Office	Pending
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2401003192	Thailand	Pending
12024551165	Philippines	Pending
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NC2024/0007518	Colombia	Pending

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24194778.7	European Patent Office	Pending
42025103259.5	Hong Kong	Pending
PI 2023000584	Malaysia	Pending
11202300697X	Singapore	Pending
19/202,059	United States of America	Pending
18/619,547	United States of America	Pending
2024242138	Australia	Pending
BR1120250210513	Brazil	Pending
3,285,080	Canada	Pending
202480023329.1	China	Pending
24716712.5	European Patent Office	Pending
62026125153.7	Hong Kong	Pending
323233	Israel	Pending
2025-556812	Japan	Pending
10-2025-7035981	Republic of Korea	Pending
826414	New Zealand	Pending
19/469,610	United States of America	Pending
1120257248	Saudi Arabia	Pending
202517099658	India	Pending
MX/a/2025/011603	Mexico	Pending
P2025-03094	United Arab Emirates	Pending
22214748.0	European Patent Office	Pending
19/659,231	United States of America	Pending
21203394.8	European Patent Office	Pending
202217076779	India	Pending
1120210243330	Brazil	Pending
122026010760-6	Brazil	Pending
18/779,611	United States of America	Pending
2023361184	Australia	Pending
3,270,486	Canada	Pending
202380080887.7	China	Pending
23 790574.0	European Patent Office	Pending
62026118839.0	Hong Kong	Pending
2025-521004	Japan	Pending
10-2025-7015515	Republic of Korea	Pending
19/119,888	United States of America	Pending
3118556	Canada	Pending
202180046533.1	China	Pending
18/748,483	United States of America	Pending
24 215587.7	European Patent Office	Pending
42025109674.9	Hong Kong	Pending
202618060740	India	Pending
PCT/EP2025/069677	WIPO	Pending
114126133	Taiwan	Pending
2024212866	Australia	Pending
3280177	Canada	Pending
202480014812.3	China	Pending
24 702075.3	European Patent Office	Pending
62026121807.2	Hong Kong	Pending
322260	Israel	Pending
2025-542221	Japan	Pending
10-2025-7027840	Republic of Korea	Pending

Patent Application Number	Jurisdiction of Filing	Status
823545	New Zealand	Pending
19/149,911	United States of America	Pending
63/957,091	United States of America	Pending
63/986,857	United States of America	Pending

Helus Pharma's patent applications cover a wide range of NSA compounds from different classes, including those with targeted structural modifications for improved pharmacokinetic characteristics and safety profiles without altering their receptor binding. The patent applications also cover novel synthetic routes, pharmaceutical formulations, methods of use, and methods of administration. As the Company generates new data it will continue to file or acquire additional patent applications throughout the Company's development program.

Additionally, the Company has entered into multiple licensing agreements that provide the Company with additional access to IP, including the acquisition of an exclusive license to a targeted class of tryptamine-based molecules from Mindset. The licensing agreements collectively provide the Company with access to a broad range of preclinical compounds to support its library of NSA derivative drug candidates.

As of November 11, 2026, the Company owns registrations or applications for fifty-nine trademarks or trademark applications.

Research and Development

The Company is focused on development of next-generation therapies, through research and development of novel chemical compounds and delivery mechanisms and study of such compounds in clinical environments around the world. The Company anticipates growing its pipeline of pharmaceutical products through its internal research, development, proprietary discovery programs, mergers and acquisitions, joint ventures and collaborative development agreements.

NSAs are a class of drug designed to activate serotonin receptors and pathways to improve brain and body function, with some NSAs causing thought, visual and auditory changes, and altered states of consciousness. The pharmacokinetics, pharmacology and human metabolism of the non-deuterated form of HLP003 are well known and well characterized. Once ingested, HLP003 acts on serotonin receptors in the brain to produce its intended effects.

The Company's research and development must be conducted in strict compliance with the regulations of federal, state, local and regulatory agencies in the United States, European Union, the UK, Australia, Poland, Greece, Ireland and Canada, and the equivalent regulatory agencies in any other jurisdictions in which the Company operates. These regulatory authorities regulate, among other things, the research, manufacture, promotion and distribution of drugs in specific jurisdictions under applicable laws and regulations.

Regulatory Framework

United States

In the United States, the FDA regulates drugs under the FFDCA and its implementing regulations, and the FDA and other U.S. federal, state and local regulatory agencies impose substantial requirements upon the clinical development, clinical testing, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of any prescription drug product candidates or commercial products. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable FDA or other requirements at any time during the product development process, approval process or after approval may result in, among other things, the FDA's delay or refusal to approve pending applications, a clinical hold, warning or untitled letters, civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market. Anticipated timelines related to regulatory filings are based on reasonable assumptions informed by current knowledge and information available to the Company.

Certain serotonergic agonists, including certain NSAs, are strictly controlled under the federal Controlled Substances Act, 21 U.S.C. § 801 et seq. ("**CSA**"), as Schedule I substances. Schedule I substances by definition have a high potential for abuse, no currently accepted medical use in the United States and a lack of accepted safety for use under medical supervision. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements, and criteria for importation. Anyone wishing to conduct research on substances listed in Schedule I under the CSA must register with the DEA and obtain DEA approval of the research proposal. A majority of state laws in the United States also classify certain serotonergic agonists, including certain NSAs, as Schedule I controlled substances. For any product containing any Schedule I substance to be available for commercial marketing in the United States, the product must be approved by the FDA through the NDA process and such substance must be rescheduled, or the product itself must be scheduled, by the DEA to Schedule II, III, IV or V (or removed from the schedules), and must also be rescheduled under applicable state controlled substance laws. Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance.

Research and Development

HLP003 and HLP004 are product candidates that would be treated as Schedule I substances under the CSA. For any Schedule I substance to be available for commercial marketing in the United States, such substance must be rescheduled, or the product itself must be scheduled, by the DEA to Schedule II, III, IV or V (or removed from the schedules).

The process required before a prescription drug product candidate may be marketed in the United States generally involves:

- completion of extensive non-clinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory, Good Clinical and/or Good Manufacturing Practice regulations;
- submission to the FDA of an IND Application, which must become effective before human clinical trials may begin, as described further below;
- approval by an IRB or independent ethics committee at each clinical trial site before each trial may be initiated;
- for nearly all new pharmaceutical products, performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the prescription drug product candidate for each proposed indication;
- submission to the FDA of a NDA, payment of applicable user fees, and a determination by the FDA within 60 days of its receipt of an NDA to accept and file the NDA for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with Current Good Manufacturing Practices ("**cGMP**") requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality, and purity;
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug; and
- for a product containing a Schedule I substance, scheduling of the FDA-approved product under the CSA and applicable state controlled substance laws to Schedules II-V (or equivalent state categories), or out of the schedules, together with implementation of any required Risk Evaluation and Mitigation Strategy ("**REMS**") and compliance with post-approval requirements.

The testing and approval process requires substantial time, effort and financial resources, and the Company cannot be certain that the DEA will schedule or reschedule any Schedule I substance or product candidate to Schedule II, III, IV, or V, or that approvals for its prescription drug product candidates will be granted on a timely basis, if at all.

Non-clinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies or through FDA-accepted alternative methods (New Approach Methodologies or NAMs). The results of non-clinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Some non-clinical testing may continue even after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator's brochure. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements.

An IRB, at each of the clinical centers proposing to conduct the clinical trial, must review and approve the plan for any clinical trial before it commences at that center. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the consent form signed by the trial participants and must monitor the study until completed. The FDA, the independent IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on its clinicaltrials.gov website, and sponsors of investigational products for serious diseases or conditions must maintain a publicly available policy on evaluating and responding to expanded access requests.

In July 2026, the FDA issued final guidance, "Psychedelic Drugs: Considerations for Clinical Investigations," finalizing the draft guidance issued in June 2023, which addresses, among other things, nonclinical, clinical and safety considerations, abuse potential assessment, risk mitigation and public health considerations for clinical investigations of psychedelic drugs, including 5-HT2 agonists. The FDA may disagree with the design or conduct of the Company's clinical trials, including in light of such guidance, which may impact the FDA's review of any NDA for the Company's product candidates.

The FDA offers a number of regulatory mechanisms that provide expedited or accelerated approval procedures for selected drugs and indications which are designed to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These include programs such as BTDs, Fast Track designation, Priority Review and Accelerated Approval, which the Company may need to rely upon in order to receive timely approval or to be competitive. As a condition of Accelerated Approval, the FDA generally requires the sponsor to conduct adequate and well-controlled confirmatory clinical trials, may require that such trials be underway prior to approval, and may use expedited procedures to withdraw approval if the sponsor fails to conduct such trials in a timely manner or if they fail to verify clinical benefit. These programs do not change the standards for approval, and the FDA may later decide that a product no longer meets the conditions for qualification.

In April 2026, the U.S. President issued Executive Order 14401, "Accelerating Medical Treatments for Serious Mental Illness," which, among other things, directs the FDA Commissioner to provide Commissioner's National Priority Vouchers to appropriate psychedelic drugs that have received Breakthrough Therapy designation and meet the criteria of the National Priority Voucher Program, directs the FDA and the DEA to establish a pathway for eligible patients to access psychedelic drugs under the Right to Try Act, and directs the Attorney General, in consultation with the U.S. Department of Health and Human Services ("HHS"), to initiate and complete review of any product containing a Schedule I substance that has successfully completed Phase 3 clinical trials for a serious mental health disorder so that rescheduling, if appropriate, may proceed as quickly as practicable following FDA approval. Additionally, in April 2026, the FDA issued national priority vouchers to programs studying psilocybin and methylone. Neither a national priority voucher nor Breakthrough Therapy designation constitutes an FDA determination of safety or effectiveness or a substitute for marketing approval, and the Company's product candidates may not qualify for or benefit from these

initiatives. In July 2026, the FDA also announced a public hearing, which was subsequently held on September 14, 2026, on considerations for the potential future therapeutic use of psychedelic drugs in supervised settings, which could inform future regulatory approaches to the delivery of psychedelic treatments.

The Company may plan to seek orphan drug designation for certain indications qualified for such designation. The United States and other jurisdictions may grant orphan drug designation to drugs intended to treat a "rare disease or condition." In the United States, this is generally a disease or condition that affects (i) fewer than 200,000 individuals in the United States, or (ii) 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the country for this type of disease or condition will be recovered from sales of the product. In the E.U., orphan drug designation can be granted if: the disease is life threatening or chronically debilitating and affects no more than 50 in 100,000 persons in the E.U.; without incentive it is unlikely that the drug would generate sufficient return to justify the necessary investment; and no satisfactory method of treatment for the condition exists or, if it does, the new drug will provide a significant benefit to those affected by the condition. In the United States, orphan drug designation must be requested before submitting an NDA. If a product that has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity, for a period of seven years in the United States and 10 years in the E.U. In the United States, orphan drug exclusivity may be revoked if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation does not prevent competitors from developing or marketing different drugs for the same indication or the same drug for different indications. After orphan drug designation is granted, the identity of the therapeutic agent and its potential orphan use are publicly disclosed. Orphan drug designation does not convey an advantage in, or shorten the duration of, the development, review and approval process. However, in the United States, a sponsor of a product that has received orphan drug designation may be granted tax credits for certain qualified clinical testing expenses, may be eligible for an exemption from certain FDA user fees and may be eligible for a waiver from the pediatric assessment requirements of the Pediatric Research Equity Act.

Depending upon the timing, duration and specifics of FDA approval, certain U.S. patents may be eligible for a patent term restoration of up to five years under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "**Hatch-Waxman Amendments**"), although restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date, and only one patent applicable to an approved drug is eligible for extension. The FFDCA also provides a five-year period of non-patent data exclusivity to the first applicant to obtain approval of an NDA for a new chemical entity, during which an ANDA or 505(b)(2) NDA for a drug containing the same active moiety generally may not be submitted (or four years if the application contains a certification of patent invalidity or non-infringement), and three years of exclusivity for an NDA or supplement supported by new clinical investigations essential to approval.

Drugs manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, and complying with promotion and advertising requirements, including restrictions on promoting drugs for uses or in patient populations not described in the approved labeling (known as "off-label use"). The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements. Any distribution of prescription drug products and samples must also comply with the Prescription Drug Marketing Act and the Drug Supply Chain Security Act. Failure to comply with statutory and regulatory requirements may subject a manufacturer to legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS.

In the United States, pharmaceutical manufacturers are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the federal Anti-Kickback Statute, the federal *False Claims Act* (the "**FCA**"), and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Remuneration has been broadly interpreted to include anything of value, and a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

The FCA prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to or approval by the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the FCA may be brought by the

government or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in very significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million- and multi-billion-dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, the federal civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. In addition, a similar federal requirement under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), commonly referred to as the "Physician Payments Sunshine Act" and implemented as the Open Payments program, requires applicable manufacturers to track and report annually to the Centers for Medicare & Medicaid Services certain payments and "transfers of value" made to physicians, teaching hospitals and certain non-physician practitioners (including physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), as well as ownership and investment interests held by physicians and their immediate family members, made in the previous calendar year. There are a number of states that have various types of additional reporting requirements.

Numerous federal and state laws, including state comprehensive privacy laws, data breach notification laws, health information privacy laws and consumer protection laws (such as Section 5 of the Federal Trade Commission Act and the California Consumer Privacy Act), govern the collection, use, disclosure and protection of health-related and other personal information. Even if the Company is not directly subject to the privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"), if it obtains health information from third parties, such as clinical trial sites, that are subject to HIPAA, it could be subject to criminal penalties if it knowingly obtains individually identifiable health information maintained by a HIPAA-covered entity in a manner not authorized by HIPAA. There is heightened sensitivity around certain types of health information, such as sensitive condition information, which may be subject to additional protections.
Any product candidates that the Company successfully commercializes, if approved, will depend on the availability and extent of coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid and commercial insurers. No uniform policy of coverage and reimbursement for drug products exists in the United States, and coverage decisions are made on a payor-by-payor basis. The Inflation Reduction Act of 2022 (the "**IRA**"), among other things, directs HHS to negotiate the price of certain single-source drugs covered under Medicare, imposes rebates under Medicare Part B and Part D for price increases that outpace inflation, and redesigned the Medicare Part D benefit, including a cap on beneficiaries' annual out-of-pocket costs

and a new Manufacturer Discount Program beginning in 2025. Legal challenges to the IRA's drug price negotiation provisions continue. In addition, on July 4, 2025, the "One Big Beautiful Bill Act" was signed into law, which is projected to reduce federal health care spending, including Medicaid spending and enrollment. On May 12, 2025, the President also issued Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," and the Administration has proposed tariffs on pharmaceutical manufacturers that do not adopt most-favored-nation pricing policies, which would tie U.S. drug prices to the lowest prices paid in certain other countries. At the state level, legislatures have increasingly enacted measures designed to control pharmaceutical costs, including prescription drug affordability boards and pricing transparency requirements.

Controlled Substances

The CSA and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the DEA. The DEA is responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV or V — with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. For any product containing a Schedule I substance to be available for commercial marketing in the United States, such substance must be rescheduled, or the product itself must be scheduled, by the DEA to Schedule II, III, IV or V. Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. To reschedule a substance or product, the DEA must conduct notice-and-comment rulemaking, including issuing an interim final rule 90 days after the later of notification of FDA approval or DEA receipt of the HHS scheduling analysis and recommendation, which is subject to public comment and requests for hearing. The final scheduling process may take significantly longer than the 90-day period, especially if there are objections, and the FDA or the DEA may require additional data regarding abuse, misuse or dependence potential, which could delay approval and rescheduling. Rescheduling, and submission of a supplemental application to the FDA to update the labeling and packaging of the drug, must occur before commercial marketing begins.

Facilities that research, manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s). For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA may inspect all research and manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration and periodically to ensure

continued compliance. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to researchers and manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

Individual U.S. states also establish and maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. A majority of state laws in the United States also treat HLP003 and HLP004 as Schedule I controlled substances. State authorities, including boards of pharmacy, regulate use of controlled substances in each state, including state-specific controlled substance registration requirements. States may separately schedule the Company's product candidates, and after FDA approval states must also reschedule a drug product containing a Schedule I substance, which may occur automatically based on federal action or may require state rulemaking or legislative action. Failure to obtain applicable registrations or maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on the Company's business, operations and financial condition. The DEA and/or state regulatory agencies may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

European Union/Netherlands

The International Narcotics Control Board ("**INCB**"), a United Nations ("**UN**") entity, monitors enforcement of restrictions on controlled substances. The INCB's authority is defined by three international UN treaties – the UN Single Convention on Narcotic Drugs of 1961, the UN

Psychotropic Convention of 1971 (referred to herein as the UN71), and the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, which contains provisions related to the control of controlled substance precursors. EU Member States, including the Netherlands, that have agreed to abide by the provisions of these treaties, each create responsible agencies and enact laws or regulations to implement the requirements of these conventions.

Specific EU legislation establishing different classes of controlled substances is limited to EU regulations that define classes of precursors, or substances used in the illicit manufacture of controlled substances, including Regulation (EC) No. 273/2004 of the European Parliament and the Council of February 11, 2004 and the Council Regulation (EC) No. 111/2005 of December 22, 2004. While EU legislation does not establish different classes of narcotic drugs or psychotropic substances, the Council Decision 2005/387/JHA of May 10, 2005 (which applies only in certain limited situations)[22] can provoke a Council Decision requiring EU member states to put a drug under national controls equivalent to those of the INCB. HLP004 is currently classified as a Schedule I substance under the UN71; the EU member states that are party to the UN71, including the Netherlands, have agreed to the following in respect of Schedule I substances:

- prohibit all use except for scientific and very limited medical purposes by duly authorized persons, in medical or scientific establishments which are directly under the control of their Governments or specifically approved by them;
- require that manufacture, trade, distribution and possession be under a special licence or prior authorization;
- provide for close supervision of the activities and acts mentioned in paragraphs (a) and (b);
- restrict the amount supplied to a duly authorized person to the quantity required for his authorized purpose;
- require that persons performing medical or scientific functions keep records concerning the acquisition of the substances and the details of their use, such records to be preserved for at least two years after the last use recorded therein; and
- prohibit export and import except when both the exporter and importer are the competent authorities or agencies of the exporting and importing country or region, respectively, or other persons or enterprises which are specifically authorized by the competent authorities of their country or region for the purpose.

As classification of controlled substances may vary among different EU member states, sponsors must be aware of the prevailing legislation in each country where a clinical trial may be conducted. Prior to operating or conducting any preclinical or clinical studies in any other EU member state, Helus Pharma will investigate the specific regulatory requirements of such EU member state. As referenced above, a licence is required for individuals and entities who wish to produce, dispense, import, or export Schedule I substances, but the specific requirements vary from country to country. Currently, DMT is classified in the Netherlands as a List 1 Drug under the Dutch Opium Act (Opiumwet) (the

[22] Decision 2005/387/JHA was repealed (by Directive (EU) 2017/2103 of the European Parliament and of the Council of November 15, 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA), but still continues to apply to new psychoactive substances in respect of which a Joint Report (as referred to in Article 5 of that Decision) has been submitted before November 23, 2018.

"**Dutch Opium Act**") and as such, subject to express authorization being obtained, the production, trade and possession of DMT are prohibited.

In addition to the Dutch Opium Act, two other Dutch Acts may be relevant when it comes to drugs: the Medicines Act and the Commodities Act.

The specific regulatory processes and approvals required may vary among different EU member states and are set forth in the respective legislation of each country. For the Netherlands, there are specific regulatory requirements for the approval of clinical trials that need to be met. Firstly, a CTA (Clinical Trial Application) dossier containing the preclinical and any clinical information along with the proposed clinical trial design must be submitted to an accredited Ethics Committee and to the Central Commission on Research in Humans (the "**CCMO**"), which is also known as the Competent Authority in The Netherlands. In Dutch, the CCMO is called the '*Centrale Commissie Mensgebonden Onderzoek*'. In cases where the study involves a substance subject to the Dutch Opium Act (such as DMT), an official exemption by Farmatec is needed, which needs to be included in the CTA.

Specific rules for the submission, assessment and conduct of clinical trials with medicinal products are set out in, among others, the EU Clinical Trial Regulation 536/2014 (CTR), which is applicable in the EU as of January 31, 2022 and the Medical Research (Human Subjects) Act (Wet medisch-wetenschappelijk onderzoek met mensen).

On April 26, 2023, the European Commission introduced a comprehensive "pharmaceutical package" aimed at revising the EU's pharmaceutical legislation. This package includes proposals for a new directive and regulation designed to enhance the availability, accessibility, and affordability of medicines. Additionally, it seeks to boost the competitiveness and attractiveness of the EU pharmaceutical industry while imposing higher environmental standards. The current status is that the European Council adopted the new rules for the "pharma package" to renovate the EU pharmaceutical legislation, and the European Parliament now still has to adopt those rules. The rules will subsequently enter into force following publication in the EU's Official Journal and will become applicable approximately end of 2028.

Research and Development

Regulation (EU) No 536/2014 on Clinical Trials on Medicinal Products for Human Use (the Clinical Trials Regulation) (the "**CTR**") is applicable as of January 31, 2022, harmonizing the laws, regulations and administrative provisions of the EU Member States relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use.[23] The CTR repealed the Clinical Trials Directive, which had previously been transformed into the respective national laws of Member States. The CTR now applies directly in all Member States without transposition being necessary. Pursuant to the CTR, as of January 31, 2023 sponsors are obliged to use the Clinical Trials Information System ("**CTIS**") for regulatory submission, authorization and supervision of clinical trials in the EU and the EEA. CTIS thus serves as the single-entry point for

[23] The CTR does not apply in the UK and UK law on clinical trials is currently based on old EU law (the Clinical Trials Directive), transposed into UK law via the Medicines for Human Use (Clinical Trials) Regulations 2004. An overhaul of UK law on clinical trials has been on-going for a few years, and new legislation on clinical trials in the UK, the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024, has been signed into law and is due to come into effect from mid-April 2026.

submissions by sponsors and for regulatory assessment. In addition to this obligation, sponsors have transferred any ongoing (approved) trials under the CTR to CTIS by January 2025. Further, EMA adopted on October 5, 2023, the "Revised CTIS Transparency Rules" on publishing information about clinical trials submitted through CTIS. To increase transparency, EMA removed the deferral mechanism which allowed sponsors to delay certain data and document publication for up to seven years after the end of their trial. Annex I of the revised rules outlines the timing of information publication for each category of clinical trial and patient population. These new rules became applicable on June 18, 2024, the same day of the launch of the new CTIS portal. In order to facilitate the process of transitioning clinical trials from the Clinical Trial Directive to the CTR, a non-binding guide named "Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation" (version 4) dated May 2024 is published.

CTIS and the practical aspects thereof are also discussed and explained (among other relevant topics relating to clinical trials) in a quick guide on the rules and procedures of the EU Clinical Trials Regulation called "Clinical Trials Regulation (EU) 536/2014 in practice", which is published by the Clinical Trials Coordination and Advisory Group ("**CTAG**") on December 8, 2023. The current version is dated March, 2024. The objective of the rules is to provide sponsors and investigators a quick guide on the rules and procedures of the CTR with a view to facilitating implementation. In addition to the quick guide, CTAG also published a non-binding Questions & Answers (Version 7.1) that should be read in conjunction with the quick guide and with the European Medicines Agency's ("**EMA**") "Clinical Trials Information System (CTIS): online training modules" in order to gain a better understanding of the legislative changes that are effected by the CTR.

The Investigational Medicinal Product Dossier ("**IMPD**") is one of several regulatory documents required for conducting a clinical trial of a pharmacologically active API intended for one or more EU Member States. The IMPD includes summaries of information related to the quality, manufacture and control of any IMP (including reference product and placebo), and data from non-clinical and clinical studies. Guidance concerning IMPDs is based on the CTR and on EMA guidelines, some of which were originally developed under the former Clinical Trials Directive but have since been updated to reflect the requirements of the CTR.

The content of the IMPD may be adapted to the existing level of knowledge and the product's phase of development. When applying for a clinical trial authorization, a full IMPD is required when little or no information about an API has been previously submitted to competent authorities, when it is not possible to cross-refer to data submitted by another sponsor and/or when there is no authorization for sale in the EU. However, a simplified IMPD may be submitted if information has been assessed previously as part of a Marketing Authorization or a clinical trial to that competent authority. Although the format is not obligatory, the components of an IMPD largely resemble the types of information required in clinical trial applications in Canada and the United States. The IMPD need not be a large document as the amount of information to be contained in the dossier is dependent on various factors such as product type, indication, development phase etc.

The assessment of an IMPD is focused on patient safety and any risks associated with the IMP. Whenever any potential new risks are identified the IMPD must be amended to reflect the changes. Certain amendments are considered substantial in which case the competent authority must be informed of the substantial amendment. This may be the case for changes in IMP impurities,

microbial contamination, viral safety, transmissible spongiform encephalopathies (e.g. mad cow disease) and in some particular cases to stability when toxic degradation products may be generated.

Pharmaceutical Products

In accordance with the Dutch Medicines Act (*Geneesmiddelenwet*), "medicinal products" are defined as: a substance or a combination of substances that is intended to be administered or used for, or is presented in any way as being suitable for, use: (i) the cure or prevention of any disease, defect, wound or pain in human beings, (ii) the making of a medical diagnosis in human beings, or (iii) restoring, improving or otherwise modifying physiological functions in humans by exerting a pharmacological, immunological or metabolic effect.

If a product constitutes a medicinal product, a marketing authorization for the product is required before the product may be placed on the market in the Netherlands. In the EU, marketing authorizations may be obtained through the Centralized procedure, the Decentralized or Mutual Recognition procedures and/or the national procedure. The Centralized procedure is compulsory for medicines intended to treat i.e. cancer, AIDS, neurodegenerative diseases and diabetes and optional for medicines comprising of new active substances not previously approved for the EEA. When applying for a marketing authorization through the Centralized procedure, applications are submitted with the EMA. Where the Centralized procedure is not available but a medicinal product is intended for several EU/EEA Member States, an application for a marketing authorization may be submitted with the competent authority of a single EU/EEA Member State in accordance with the Decentralized procedure. When the assessment of the application results in a decision to grant the marketing authorization, this decision will be recognized by the competent authorities of the other Member States for which the marketing authorization is applied. The Mutual Recognition procedure is similar to the Decentralised procedure, but applies to applications where the medicinal product is already the subject of a marketing authorization in another EU/EEA Member State. Finally, should a medicinal product be intended for the Netherlands only, then the national procedure may be followed by submitting an application with the Dutch Medicines Evaluation Board. It may be remarked that the national procedure is unavailable in case the Centralized procedure is compulsory or in case an applicant has already submitted an application for and/or obtained a marketing authorization in another Member State. In that case, applications must follow the Mutual Recognition procedure instead.

Companies that manufacture or trade in medicinal products and/or active pharmaceutical ingredients in the Netherlands require a manufacturing authorization or a wholesale distribution authorization. A manufacturing authorization is required for the preparation, trading in, import and export of medicinal products and/or active substances. Here, 'preparation' means the total or partial manufacture of medicinal products and/or active substances or the packaging or labelling thereof. 'Importing' means the import of medicinal products or active substances from a country outside the EEA into the Dutch territory, while 'exporting' means the export of medicinal products or active substances from the Dutch territory to a country outside the EEA. A wholesale distribution authorization is required for one or more activities within the wholesale business, such as procuring, holding, supplying, delivering or exporting medicinal products or active substances which are prepared or imported by a third party. It may be noted that holders of wholesale distribution authorization, other than holders of marketing authorizations, are not authorized to import medicinal products from countries outside the EEA.

Only a natural or legal person established in the Netherlands, or another EU Member State, may obtain either a Dutch marketing authorization or a wholesale distribution authorization. These authorizations concern national permits, meaning that these authorizations are not automatically valid in other EU Member States. Furthermore, in the Netherlands applicants of marketing authorizations and wholesale distributions authorizations must be registered with Farmatec and comply with GDP norms.

Marketing Authorization Regulatory Process

Under the Centralized procedure, pharmaceutical companies submit a single marketing authorization application to the EMA, which provides the basis of a legally binding recommendation that will be provided by the EMA to the European Commission, the authorizing body for all centrally authorized products. This allows the marketing-authorization holder to market the medicine and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorization. EMA's Committee for Medicinal products for Human Use or Committee for Medicinal Products for Veterinary Use carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not, under any particular dosing regime. Although, under EU law, the EMA has no authority to permit marketing in the different EU countries, the European Commission is the authorizing body for all centrally authorized products, who takes a legally binding decision based on EMA's recommendation. Once granted by the European Commission, the centralized marketing authorization is valid in all EU Member States as well as in the European Economic Area countries Iceland, Liechtenstein and Norway. European Commission decisions are published in the Community Register of medicinal products for human use. Once a medicine has been authorized for use in the EU, the EMA and the EU Member States constantly monitor its safety and take action if new information indicates that the medicine is no longer as safe and effective as previously thought. The safety monitoring of medicines involves a number of routine activities ranging from: assessing the way risks associated with a medicine will be managed and monitored once it is authorized; continuously monitoring suspected side effects reported by patients and healthcare professionals, identified in new clinical studies or reported in scientific publications; regularly assessing reports submitted by the Company holding the marketing authorization on the benefit-risk balance of a medicine in real life; and assessing the design and results of post-authorization safety studies which were required at the time of authorization. The EMA can also carry out a review of a medicine or a class of medicines upon request of a Member State or the European Commission. These are called EU referral procedures; they are usually triggered by concerns in relation to a medicine's safety, the effectiveness of risk minimization measures or the benefit-risk balance of the medicine. The EMA has a dedicated committee responsible for assessing and monitoring the safety of medicines, the Pharmacovigilance Risk Assessment Committee. This ensures that EMA and the EU Member States can move very quickly once an issue is detected and take any necessary action, such as amending the information available to patients and healthcare professionals, restricting use or suspending a medicine, in a timely manner in order to protect patients.

Besides the Centralized procedure, pharmaceutical companies may also submit marketing authorization applications through the Decentralized procedure with the competent authority of a Member State. As the Centralized procedure is compulsory for medicines intended to treat specified diseases e.g. cancer, AIDS, neurodegenerative diseases and diabetes and optional for medicines

comprising of new active substances not previously approved for the EU/EEA, in all other circumstances the Decentralized procedure should be used instead if a marketing authorization is to be obtained for several EU/EEA Member States. When following the Decentralized procedure, the applicant requests one country to be the Reference Member State ("**RMS**") in the procedure. After having shared draft assessment reports to which both the applicant and the competent authorities of other Member States may respond, the Decentralized procedure results in coordinated national marketing authorization in all involved Member States. In the Mutual recognition procedure other Member States generally adopt the RMS's assessment, unless there are important objections on the grounds of a potentially serious risk to public health. In such situations, further discussions will also be held in the Co-ordination group for Mutual recognition and Decentralised procedures ("**CMDh**"). When all Member States involved decide on a positive opinion on products in the CMDh, Dutch translations of the summary of product characteristics, package leaflet, labelling texts and mock-ups are submitted and a national marketing authorization is issued.

United Kingdom

In the UK, there are two main "layers" of regulation with which products containing controlled substances must comply. These are: (i) controlled drugs legislation, which applies to all products irrespective of the type of product, and (ii) the regulatory frameworks applicable to a specific category of products, in this case, pharmaceuticals and food/food supplements.

The main UK controlled drugs legislation is the Misuse of Drugs Act 1971 (the "**MDA**") and the Misuse of Drugs Regulations 2001 (the "**MDR**"), applicable in Great Britain (England, Scotland and Wales) and the Misuse of Drugs Regulations (Northern Ireland) 2002 (the "NIMDR") applicable in Northern Ireland, each as amended. The MDA sets out the penalties for unlawful production, possession and supply, and the offering to supply, of controlled drugs based on three classes of risk (A, B and C). The MDR and NIMDR set out the permitted uses of controlled drugs based on which Schedule (1 to 5) they fall within.

In the United Kingdom, HLP003 and HLP004 are controlled as a Class A drug under the MDA and Schedule 1 drug under both the MDR and NIMDR.

In the United Kingdom, Class A drugs are deemed to be the most dangerous, and so carry the harshest punishments for unlawful manufacture, production, possession and supply. Schedule 1 drugs can only be lawfully manufactured, produced, possessed, supplied or offered for supply under a controlled drugs domestic licence, which specifies the specific activities to which it relates together with any applicable conditions. This license is issued by the UK Home Office in respect of sites in Great Britain and the Department of Health Northern Ireland in respect of sites in Northern Ireland. While exemptions do exist, none are applicable to the API. DMT is also considered a Class A drug under the MDA and as a Schedule I drug under the MDR and NIMDR.

The Company previously mentioned that it intended to file a clinical trial application with the UK Medical and Healthcare products Regulatory Agency ("**MHRA**") related to the HLP003 Program upon completion of its pre-clinical studies and CMC development. The Company had then decided that it would first proceed in the U.S. and would subsequently file a clinical trial application with the MHRA. On July 17, 2025, the Company announced that it has received approval from the MHRA to

commence EMBRACE, the second pivotal study in PARADIGM. Anticipated timelines related to regulatory filings are based on reasonable assumptions informed by current knowledge and information available to the Company.

Licensing Requirements

The Company obtains HLP003 API from a pharmaceutical ingredient provider who is FDA-registered and based in the United States. The API itself has been manufactured and packaged in FDA-registered facilities in the United States. The API is expected to be sent directly to the Company's partners for research and development purposes in the United States, Canada and the UK and to its clinical trial sites in the U.S., Europe, the UK and Australia. As a part of the Asset Acquisition, the Company also acquired API. The HLP004-E API was manufactured in the Netherlands by a pharmaceutical ingredient provider that is US FDA-inspected.[24]

As mentioned above, in order to produce, possess and supply the API at a UK-based facility, the facility must also hold a domestic license issued by the Home Office or the Department of Health Northern Ireland, as appropriate, covering the manufacture, production, possession and supply of a controlled substance. For export of the API to the United States, an export license is required for each API shipment. The export application must include details of the importer and any import license required by the local authorities in the United States. Moreover, as set out below in more detail under the heading "Pharmaceutical Products", depending on how the API is developed and supplied, certain authorizations and licenses from the MHRA may be required to authorize some of the activities carried on at the UK-based facilities in relation to the API.

All premises that are licensed by the Home Office or Department of Health Northern Ireland, or are intending to be licensed, in connection with the possession, and/or supply and/or production of controlled drugs should consider certain security measures.[25]

Typically, when controlled drugs are being transported between licensees, responsibility for their security remains with the owner and does not transfer to either the courier or the customer until the drugs arrive at their destination and are signed for. However, where a third party is involved in the transit and/or storage of controlled drugs, even if they are not the legal owners, this party also carries responsibility for their security by virtue of being 'in possession' of them. The MDA requires that every UK entity in possession of controlled drugs holds an appropriate domestic licence and under the Home Office guidance, each UK organization involved in the movement of controlled drugs should have a standard operating procedure covering their responsibilities, record keeping, reconciliation and reporting of thefts/losses.[26]

Cybin Ireland, the sponsor of clinical trials in the UK, is not required to hold a Controlled Drugs Licence as an Irish entity.

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[24] As a result of the Asset Acquisition, including the existing API, the Company did not direct the manufacturing of the API for HLP004-E and proceeded in reliance upon the representations of Entheon and the Company's acquisition diligence. While the Company believes the HLP004-E API meets all required specifications, the Company did not oversee or direct the manufacture of the DMT API being used in HLP004-E.

[25] Home Office guidance; Security guidance for all existing or prospective Home Office Controlled Drug Licensees and/or Precursor Chemical Licensees or Registrants; 2022; https://assets.publishing.service.gov.uk/media/63a1b6c8e90e075874d91825/Security_Guidance_for_all_Businesses_and_Other_Organisations_v1.5_Nov_2022.pdf

[26] Home Office guidance; Guidelines for Standard Operating Procedures (SOPs);_https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/480572/StandardOpProcedure.pdf.

Pharmaceutical Products

A product is regulated as a "medicinal product" under UK legislation (the Human Medicines Regulations 2012, as amended) if (i) it is a substance or combination of substances presented as having properties of preventing or treating disease in human beings (e.g., in marketing claims) or (ii) it is a substance or combination of substances that may be used by or administered to human beings with a view to (a) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or (b) making a medical diagnosis.

In respect of HLP003 and HLP004, whether a specific product restores, corrects or modifies a physiological function by exerting a pharmacological, immunological or metabolic action will depend on factors such as the concentrations of HLP003 or HLP004 (as applicable) and the mode of action of any HLP003 or HLP004 (as applicable) absorbed in the body. This requires scientific analysis.

If a product is a medicinal product, the Human Medicines Regulations 2012 require that a marketing authorization for the product granted by the UK Licensing Authority must be in place before the product is placed on the market in the UK (other, more limited, licensing options are available, such as a conditional marketing authorization), unless the product falls within one of the specified exemptions, such as supply in response to an unsolicited request from a healthcare professional to meet the special clinical needs of a particular patient under his/her care. Following the UK's exit from the EU and the end of the transitional period, up to (and including) December 31, 2024, there were separate licensing routes and licences for products supplied: (i) in Great Britain only; (ii) in Northern Ireland only; and (iii) across the UK. From January 1, 2025, the UK Licensing Authority now licenses products across the whole of the UK through UK-wide licenses, removing the separate licensing routes for Great Britain and Northern Ireland for many medicinal products. The process for obtaining a standard marketing authorization generally involves submitting preclinical and clinical data as well as quality and manufacturing information in the form of a common technical document to the MHRA. In addition to a marketing authorization for the product itself, companies carrying out activities involving medicinal products, such as manufacturing, distribution and wholesaling, need to meet defined standards (Good Manufacturing Practices ("**GMP**") and/or Good Distribution Practice ("**GDP**")) and to hold a related licence from the MHRA.

How the API is subsequently processed will determine the licences (in addition to any applicable domestic controlled drug licences as referred to above) that the UK-based facility must hold. In particular:

- if the API is just one 'ingredient' (i.e. active substance) of the investigational medicinal product (the "**IMP**") which is used in the clinical trial and the facility will not manufacture the finished medicinal product, then the UK-based facility must apply to be registered with the MHRA and provide the MHRA with 60 days' notice of the intended start of manufacture, import or distribution of the API, and comply with GMP and GDP for active substances. Furthermore, an MHRA inspection may be required; and
- conversely, if the API will itself constitute the IMP, the manufacturer must, except in certain limited circumstances, hold a Manufacturer's Authorizations for IMPs licence ("**MIA(IMP)**") granted by the MHRA. In this scenario, assuming the IMP is manufactured or assembled in

the UK, an MIA(IMP) would be required regardless of whether the IMP is for use in clinical trials in the UK, an EEA Member State or a third country (such as the United States or Canada). GMP, GDP and inspection requirements will apply.

Some products fall on the borderline between medicines and other categories of regulated products such as medical devices, cosmetics or food supplements. The regulatory status of the product will be determined by i) the actual effect of the product on the body; and ii) any claims made about the effect of the product. Where a product is potentially both a medicinal product and another category of product, the legal position in the UK and EU is that it will be regulated as a medicinal product.

Australia

The Australian regulatory framework for therapeutic goods (i.e. medicines) and clinical trials is overseen by the Therapeutic Goods Administration (the "**TGA**").

In most cases, the Therapeutic Goods Act 1989 (Cth) (the "**TG Act**") requires that medicines must be entered on the Australian Register of Therapeutic Goods before they can be imported into and/or supplied in Australia. However, in some circumstances the TGA permits access to unapproved therapeutic goods as part of clinical trials, or via a prescription from an authorized clinician.

In Australia, the regulations applicable to certain drugs are determined by their classification under the Therapeutic Goods (Poisons Standard—October 2025) Instrument 2025 (Poisons Standard), a legislative instrument made under the TG Act and maintained by the TGA.

The Poisons Standard is given legal effect and enforced through State and Territory legislation, regulations and instruments across Australia, including:

- Australian Capital Territory: Medicines, Poisons and Therapeutic Goods Act 2008 (ACT); Medicines, Poisons and Therapeutic Goods Regulation 2008 (ACT);
- New South Wales: Poisons and Therapeutic Goods Act 1966 (NSW); Poisons and Therapeutic Goods Regulation 2008 (NSW);
- Northern Territory: Medicines, Poisons and Therapeutic Goods Act 2012 (NT); Medicines, Poisons and Therapeutic Goods Regulations 2014 (NT);
- Queensland: Medicines and Poisons Act 2019 (Qld); Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 (Qld); Medicines and Poisons (Medicines) Regulation 2021 (Qld); Medicines and Poisons (Pest Management Activities) Regulation 2021 (Qld);
- South Australia: Controlled Substances Act 1984 (SA); Controlled Substances (Poisons) Regulations 2011 (SA); Controlled Substances (Controlled Drugs, Precursors and Plants) Regulations 2014 (SA);
- Tasmania: Poisons Act 1971 (Tas); Poisons Regulations 2018 (Tas);
- Victoria: Drugs, Poisons and Controlled Substances Act 1981 (Vic) and Drugs, Poisons and Controlled Substances Regulations 2017 (Vic); and

- Western Australia: Medicines and Poisons Act 2014 (WA); Medicines and Poisons Regulations 2016 (WA).

Schedule 8 of the Poisons Standard lists controlled drugs which are only available for therapeutic use via a prescription for certain indications. These drugs are subject to more stringent controls than other prescription medicines because of the relatively greater risk of misuse. Schedule 9 of the Poisons Standard contains prohibited substances which cannot be used without regulatory approvals (for example, approvals for use in clinical trials) because these substances have been deemed to have a higher risk of abuse, misuse or diversion.

HLP003 and HLP004 are prohibited substances under Schedule 9 of the Poisons Standard. The use and supply of these substances is only permitted under the TGA's Authorized Prescriber Scheme, the Special Access Scheme and clinical trials approved by, or notified to, the TGA.

The importation of schedule 9 drugs is prohibited and the importation and/or supply of a prohibited substance without the relevant approvals is a criminal offence. Approvals must be obtained from the TGA and the Office of Drug Control to import HLP003 for the purpose of conducting clinical trials.

Under section 19 of the TG Act, the TGA may grant approval for the importation and/or supply of unapproved therapeutic goods to a clinician for use in the treatment of a patient, or solely for experimental purposes in humans. The Office of Drug Control also regulates the importation of psychotropic substances and a licence must be issued by the Narcotics Control Section in order to import HLP003 into Australia. Individual permits must then be obtained for each consignment of HLP003. Further licences and/or permits must be sought from the State or Territory health authority in the State or Territory in which the trial is to be conducted, in order to manufacture, possess, supply or use schedule 9 drugs for clinical trials. The specific regulations applicable will depend on the State or Territory in which these acts occur.

By way of example, in New South Wales section 17D of the Poisons and Therapeutic Goods Act 1966 (NSW) enables the Secretary of the New South Wales Ministry of Health to authorize a person to manufacture, possess, use or supply a specified Schedule 9 substance. The conditions of any authorization obtained in New South Wales can also include additional restrictions on the personnel authorized to use Schedule 9 substances in the trial and further storage, handling and disposal requirements. Meanwhile, in the state of Victoria, an additional licence/permit is also required to import schedule 9 drugs.

Clinical trials

All clinical trials conducted in Australia must have a local sponsor (an overseas company cannot be the sponsor of a clinical trial conducted in Australia). The trial sponsor is responsible for the initiation, management and financing of the trial and carries the legal risk arising from the conduct of the trial. The sponsor must also ensure that the use of therapeutic goods in the trial must be in accordance with the Guideline for Good Clinical Practice, the National Statement on Ethical Conduct in Research

Involving Humans and the protocol approved by the HREC responsible for monitoring the conduct of the trial.

Clinical trials involving unapproved therapeutic goods, including products containing HLP003, may be conducted in Australia under two schemes: Clinical Trial Notification (the "**CTN**") or Clinical Trial Approval (the "**CTA**"). The Australian clinical trial involving HLP003 was approved through the CTN scheme, obtained clearance from multiple Ethics Committees of the TGA, and the study site Research Governance Offices.

Under the CTN scheme the TGA does not review or evaluate any data relating to clinical trials. All material relating to the proposed trial, including the trial protocol is submitted directly to, and reviewed by the HREC and the site where the trial will be conducted. The CTN scheme can be used where a foreign regulator with comparable regulatory requirements has already approved a clinical trial for an equivalent indication.

A clinical trial is deemed to be notified by the TGA, after the CTN form has been submitted to the TGA and the relevant fee has been paid. Once that occurs, the CTN exemption comes into effect and the trial sponsor can lawfully supply the goods.

Under the CTA scheme, the TGA will review and evaluate relevant, but limited, scientific data (which may be preclinical and early clinical data) prior to the start of a trial. The TGA's primary responsibility is to review the safety of the product and the HREC is responsible for considering the scientific and ethical issues of the proposed trial protocol. Conduct of a clinical trial under the CTA scheme must also be approved by the responsible HREC.

Throughout the conduct of the trial, sponsors must ensure that any advertisements and promotional materials relating to the trial do not promote the use of unapproved therapeutic goods. However, materials promoting clinical trials directly to clinicians fall outside of these restrictions.

Upon the completion of the Australian trial, it will not be possible to make an application to register HLP003 on the Australian Register of Therapeutic Goods because non-deuterated HLP003 is currently listed in schedule 9 of the Poisons Standard. However, this may be possible if an application is made to the TGA to change the scheduling of HLP003 so that it is removed from Schedule 9 of the Poisons Standard.

In some circumstances it is possible for clinicians to import and then supply unapproved therapeutic goods, including schedule 9 drugs, to patients. The Special Access Scheme (the "**SAS**") permits approved clinicians to prescribe Schedule 9 drugs to individual patients in limited circumstances. Category A of the SAS enables medical practitioners to access unapproved therapeutic goods for a patient who is seriously ill. Clinicians who are unable to access HLP003 through the Category A can also seek approval to access HLP003 for patients on a case by case basis under Category B of the SAS.

Meanwhile, medical practitioners who wish to prescribe HLP003 to more than one patient can seek to become an authorized prescriber. The medical practitioner must first obtain approval for the proposed

use of HLP003 from a human research ethics committee (because the TGA does not consider that non-deuterated forms of HLP003 have an established history of use) and then make an application to the TGA.

Poland

The manufacture, trade, processing, possession, use and distribution of narcotic drugs, psychotropic substances and new psychoactive substances in Poland are governed primarily by two legal acts: the Act of July 29, 2005 on Counteracting Drug Addiction (the "**ACDA**"), and the Act of September 6, 2001 the Pharmaceutical Law (the "**PLA**").

Under the ACDA, psychotropic substances are defined as substances of natural or synthetic origin, in pure form or in the form of a preparation, acting on the central nervous system.

Psychotropic substances are divided into four groups: I-P, II-P, III-P and IV-P. Narcotic drugs are analogously divided into groups I-N to IV-N. The classification is based on the risk of abuse and dependence and the extent of recognised medical use.

According to the ACDA narcotic drugs of groups I-N and II-N and psychotropic substances of groups II-P, III-P and IV-P may only be used for medical, industrial or research purposes. Psychotropic substances of group I-P may be used exclusively for scientific research purposes. This is due to the fact that psychotropic substances classified to group I-P substances are considered the most dangerous, with a high potential for abuse and no accepted medical use under current Polish law.

HLP003 and HLP004 are strictly controlled substances. According to the Ordinance of the Minister of Health of 17 August *2018 on the list of psychotropic substances, narcotic drugs and new psychoactive substances (Rozporządzenie Ministra Zdrowia z dnia 17 sierpnia 2018 r. w sprawie wykazu substancji psychotropowych, środków odurzających oraz nowych substancji psychoaktywnych*), HLP003 and HLP004 are classified as group I-P psychotropic substances. Thus, for any product containing HLP003 or any group I-P psychotropic substances to be available for commercial marketing in Poland, such substance must be first reclassified/reassigned to another group.

Only strictly defined entities specified in the ACDA may possess narcotic drugs, psychotropic substances and new psychoactive substances or their preparations, i.e. entrepreneurs holding appropriate permits, scientific institutions, or entities additionally specified in Regulation 273/2004 or Regulation 111/2005. Undertaking activities involving the manufacture, processing, conversion, import, or distribution of narcotic drugs or psychotropic substances requires an appropriate authorization issued by the national authorities. Authorization is also required for the manufacture, processing, or conversion of such substances for the purpose of conducting scientific research by scientific institutions within the scope of their statutory activities, in relation to narcotic drugs of groups I-N, II-N, and IV-N, or psychotropic substances of groups I-P, II-P, III-P, and IV-P. A separate authorization is additionally required for the use of narcotic drugs or psychotropic substances for the purpose of conducting scientific research by scientific institutions within the scope of their statutory activities.

Obtaining the required authorizations involves meeting numerous criteria set out in detail in the ACDA and in the Ordinance of the Minister of Health of 9 November 2015 on the issuance of permits

for the manufacture, processing, conversion, import, distribution or use for scientific research purposes of narcotic drugs, psychotropic substances or category 1 precursors (*Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2015 r. w sprawie wydawania zezwoleń na wytwarzanie, przetwarzanie, przerabianie, przywóz, dystrybucję albo stosowanie w celu prowadzenia badań naukowych środków odurzających, substancji psychotropowych lub prekursorów kategorii 1*).

The criteria include, among others: maintaining adequate procedures and internal control systems, employing a qualified person responsible for supervision of narcotics and psychotropics, ensuring physical security of premises (two-lock doors, alarm system, reinforced windows, safes or fixed metal cabinets), maintaining inventory and turnover records. In the case of conducting scientific research, it is also necessary to:

- define the purpose and scope of the research, as well as the methods for sample preparation and analysis of research results;
- submit to the regulatory authority a copy of the institution's statute and a commitment to provide copies of any amendments to the statute;
- specify the planned start and end dates of the research; and
- in the case of manufacture, processing, or conversion of narcotic drugs of groups I-N, II-N, and IV-N or psychotropic substances of groups I-P, II-P, III-P, and IV-P, maintain documentation of technically justified standards for the consumption of raw materials used in the process, as well as the acceptable loss rates at each stage of production.

The records of narcotic drugs, psychotropic substances, and precursors must be kept in a way that allows easy tracking of all events and transactions related to them, especially those involving the receipt and release of these substances. A separate control book must be kept for each narcotic and psychotropic substance (by group and dosage), recording receipts, issues, stock levels, and remarks. Entries are made by qualified person. The control book is retained for five years from the beginning of the year following the last entry.

Unlawful manufacturing, processing or conversion of narcotic drugs or psychotropic substances is subject to imprisonment for up to three years. In the case of significant quantities of narcotic drugs or psychotropic substances, the perpetrator is liable to a fine and imprisonment for three to 20 years. Narcotic drugs, psychotropic substances, new psychoactive substances, or their preparations, as well as category 1 precursors, possessed without authorization, are subject to seizure by law enforcement or customs authorities in the manner specified in criminal procedure. Seized products are subject to forfeiture of the goods to the benefit of the State Treasury.

Clinical (scientific) research involving psychotropic substances is regulated by several legal acts, including the ACDA, the PLA, the Act of March 9, 2023, on clinical trials of medicinal products used in humans, Regulation (EU) No 536/2014 of April 16, 2014, on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, as well as implementing acts and regulations, including the Ordinance of the Minister of Health of November 9, 2015, on the issuance of permits for the manufacture, processing, conversion, import, distribution, or use for scientific research purposes of narcotic drugs, psychotropic substances, or category 1 precursors. Only entities authorized for this

purpose may conduct scientific studies involving psychotropic substances from group I-P, including, for example, universities, scientific institutes and research institutes.

Clinical trials involving psychotropic substance are legally possible only as scientific research, and only after obtaining all of the following approvals, including authorization to use the I-P psychotropic substance for research, positive opinion of a Bioethics Committee, clinical-trial authorization, as well as all permits required for handling a controlled substance, such as authorizations for manufacture, processing, conversion, import, export, intra-EU acquisition, and intra-EU supply of narcotic drugs and psychotropic substances.

All stages of the study must comply with the Good Clinical Practice ("**GCP**") standards, relevant EU and national data protection, pharmacovigilance, and biosafety regulations, and the ethical principles set out in the Declaration of Helsinki. Given the high risk of abuse of group I-P substances, the scientific institution must maintain secure storage conditions (in line with the standards included in the Ordinance of the Minister of Health of November 9, 2015), keep detailed logs of the quantity, source, and use of each psychotropic substance, and report any discrepancies or losses immediately to the competent authorities.

Under the current ACDA, medicinal products containing group I-P substances cannot be granted marketing authorization, as the use of such substances is permitted only for research purposes. This prohibition effectively prevents them from being included in authorized medicinal products. Obtaining a marketing authorization would thus require first a reclassification of the substance (from group I-P to II-P or lower). Medicinal products containing psychotropic substances may be authorized and marketed in Poland only if they meet the definition of a medicinal product under the PLA and comply with all ACDA restrictions applicable to controlled substances. According to the PLA, a medicinal product is any substance or combination of substances presented for preventing or treating disease in humans or animals, or administered with a view to making a diagnosis or restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action.

Marketing authorization of a medicinal product can be obtained through several procedures, depending on the product type and the geographical scope:

- National Procedure – authorization is granted by the national authority - the Office for Registration of Medicinal Products. The authorization is valid only in Poland.
- Decentralised Procedure – used for products not yet authorized in any EU Member State. The applicant applies simultaneously in several countries, with one acting as the Reference Member State ("**RMS**").
- Mutual Recognition Procedure – used when a product is already authorized in one EU Member State. Other countries recognize this authorization based on the RMS assessment.
- Centralised Procedure – conducted by the EMA. Once approved by the European Commission, the authorization is valid across all EU and EFTA countries.

Medicinal products that have obtained a marketing authorization issued by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products may be lawfully placed on the market.

The application for a marketing authorization of a medicinal product must include documentation confirming its manufacturing process, quality control, safety, and efficacy. Specifically:

- description of manufacturing process and quality control methods,
- written confirmation of GMP audit for the active substance manufacturer,
- information on storage, dispensing, and disposal, including environmental risk assessment,
- results and summaries of pharmaceutical, non-clinical, and clinical studies,
- summary of the pharmacovigilance system, including declarations from the marketing authorization holder and details of the qualified person,
- risk management plan for the product's use,
- ethical compliance statement for clinical trials conducted outside the EU/EFTA,
- expert declarations of qualifications,
- summary of Product Characteristics,
- mock-ups of packaging and patient leaflet, with a readability test report,
- copies of authorizations, decisions, and related documents from EU, EFTA, or third countries,
- list of countries where the application is under review, and
- copy of the manufacturing authorization from the production site.

By way of a separate national regulation, the Minister of Health indicates psychoactive substances and their maximum content in medicinal products necessary for effective treatment within the acceptable period of safe treatment for one person. This obligation is intended to limit the dispensing of medicinal products in single sales, with a view to protecting public health and the safety and efficacy of medicinal products, as well as their dosage.

Greece

The Company's development activities in Greece relate to its multinational pivotal clinical program evaluating HLP003 for the potential adjunctive treatment of MDD (EMBRACE). The Company has received European approval to initiate the EMBRACE study in selected EU Member States, including Greece, and will conduct any activities in Greece in accordance with applicable EU and Greek legal and regulatory frameworks governing investigational medicinal products and controlled substances.

In Greece, controlled substances are regulated under national legislation implementing the UN Single Convention on Narcotic Drugs (1961), the UN Convention on Psychotropic Substances (1971) and related EU law, including Greek Law 4139/2013 on addictive substances (Government Gazette A' 74/20.03.2013), as amended and in force, the tables of controlled substances (Tables A to D) originally set out in Article 1 of Law 3459/2006 (Code of Laws on Narcotics), as amended by ministerial decisions, and Presidential Decree 148/2007 (codification of regulatory decrees and ministerial decisions of the national legislation on narcotics). Psilocybin and psilocin, together with their salts and isomers, are listed in Table A, which comprises the substances subject to the strictest level of control in Greece. HLP003, as a controlled substance, is subject to strict prohibitions on manufacture, possession, distribution, import and export, unless expressly authorized for scientific or very limited medical purposes by duly authorized persons or entities, operating under licence and

subject to stringent security, recordkeeping and oversight requirements. Under Law 4139/2013, the production, possession, transport, storage, supply, processing and circulation of Table A substances is an exclusive right of the Greek State exercised through the Greek National Organization for Medicines (the "**EOF**"), and such substances may only be made available to laboratories or hospitals for the performance of approved programs, following an opinion of the Narcotics Committee established within the Ministry of Health. Licences for the import and export of controlled substances are granted by decision of the Ministry of Health, following an opinion of the Narcotics Committee, and overall control and supervision of narcotics is exercised by the Ministry of Health. As an EU Member State, Greece applies the CTR, including the Clinical Trials Information System for submissions, supervision and transparency. The national provisions for the application of the CTR are set out in Ministerial Decision Γ5α/59676/2016 (Government Gazette B' 4131/22.12.2016), pursuant to which the EOF is the competent authority and national contact point for the CTR, while the National Ethics Committee is responsible for issuing opinions on the ethical aspects (Part II) of clinical trial applications.

Clinical trials in Greece involving controlled substances require all standard clinical trial approvals under the EU Clinical Trials Regulation, together with any specific national licences and permits applicable to the handling, storage, receipt, use, transport, import and export of the relevant controlled substances at trial sites and other facilities involved in the conduct of the study. Compliance includes, among other obligations, appropriate physical security, access controls, inventory reconciliation, documentation and retention, diversion prevention and incident reporting. Additionally, import and export of controlled substances are subject to prior authorization and documentation by the competent authorities pursuant to Article 2(5) of Law 4139/2013 (licence granted by decision of the Ministry of Health following an opinion of the Narcotics Committee) and the relevant codified provisions under Presidential Decree 148/2007, as well as the requirements of the exporting and importing jurisdictions.

Helus Pharma does not itself manufacture, handle or distribute controlled substances in Greece. The Company sponsors and oversees clinical research conducted by licensed third-party institutions and clinical sites, that are responsible for obtaining and maintaining all applicable Greek licences, permits and authorizations for controlled substances and investigational medicinal products, and for ensuring site-level compliance with the Clinical Trials Regulation, current GCP standards, and Greek controlled drug requirements under Law 4139/2013, including security, storage, documentation, and reporting obligations. Helus Pharma continues to monitor compliance through its quality and clinical governance systems and relies on contractual undertakings, ongoing oversight, and representations and warranties from its partners and vendors with respect to regulatory compliance.

Any future commercialization of the HLP003 product would require marketing authorization ("**MA**") and continued compliance with applicable controlled-substance controls, pharmacovigilance, labelling, GDP/GMP and other requirements. Pharmaceutical products in Greece are regulated primarily under the EU and national frameworks implementing Directive 2001/83/EC and Regulation No. 726/2004. Products authorized through the EU centralized procedure receive a single marketing authorization issued by the European Commission, which is automatically valid in all EU Member States, including Greece.

While the centralized MA permits marketing throughout the EU, national-level compliance obligations remain in place, including:

- Pricing and reimbursement procedures before the Ministry of Health, including health technology assessment by the Committee for the Evaluation and Reimbursement of Medicinal Products for Human Use and price negotiation by the Medicines Price Negotiation Committee under Law 4512/2018, as well as, where applicable, inclusion in the Innovation Fund established by Law 5302/2026 for advanced therapy (ATMP) and PRIME medicinal products;
- Notification to EOF prior to product launch in the national market;
- Pharmacovigilance and safety reporting obligations in accordance with Regulation (EU) No. 1235/2010 and Directive 2010/84/EU;
- GMP and GDP requirements, implemented through Greek secondary legislation, principally Joint Ministerial Decision ΔΥΓ3α/Γ.Π. 32221/2013 (Government Gazette B' 1049/29.04.2013), which transposes Directive 2001/83/EC into Greek law;
- Greek-language labelling and patient information leaflet requirements; and
- Restrictions on advertising and promotion, as applicable.

For centrally authorized medicinal products containing controlled substances, additional Greek licensing and notification requirements apply for importation, distribution, and storage, consistent with the national controlled substance framework under Law 4139/2013. EOF may require confirmation of appropriate site licences prior to allowing local supply chain activities. To be noted that changes to Greek or EU legislation, regulations, scheduling or enforcement priorities could increase compliance burdens, delay clinical timelines, or adversely affect the Company's operations in Greece.

As of the date of this MD&A, to the Company's knowledge, the Company is in compliance with applicable EU and Greek laws and the related licensing frameworks, as they pertain to the Company's activities in Greece conducted through authorized third parties. The Company and, to its knowledge, its third party researchers and suppliers have not received any notices of violation that may have a material impact on the Company's licences, business activities or operations in Greece.

Ireland

In Ireland, HLP003 is a controlled substance under the *Misuse of Drugs Act, 1977, 1984 and 2015* (the "**Ireland MDA**"), the *Misuse of Drugs Regulations 2017* (the "**Ireland MDR**") and the *Criminal Justice (Psychoactive Substances) Act 2010* (the "**2010 Act**"). These are the primary legislative instruments which govern controlled substances in Ireland. This legislation regulates the use, possession, supply, licensing, and administration of listed scheduled substances and establishes the offences and penalties for infringement of the legislation.

Any substance, product or preparation (whether natural or otherwise) containing HLP003 is classed as a controlled substance under the Schedule to the Ireland MDA and Schedule 1 to the Ireland MDR. Accordingly, HLP003 is subject to the strict regime of control that applies.

As a controlled substance under the Schedule to the Ireland MDA, unlawful manufacturing, production, preparation, importation, exportation, supply, or distribution of scheduled controlled substances carries onerous obligations and harsh punishments for contravention; this includes prohibition orders, closure orders, fines and/or terms of imprisonment of up to 14 years or imprisonment of up to life when the value of the controlled substance is €13,000 or more. The Gardaí and Customs officials are granted powers to search persons, vehicles, premises and postal packages suspected of possessing/containing a controlled substance and/or a psychoactive substance for human consumption.

Pursuant to section 14 of the Ireland MDA, in certain circumstances, the Minister for Health "may grant licences or issue permits or authorizations for any of the purposes of this Act, attach conditions to any such licence, permit or authorization, vary such conditions and revoke any such licence, permit or authorization". Where licences are granted, there are very strict conditions imposed on licence holders. For example, strict conditions can be placed regarding the security, storage and documenting controlled substances. Further, the 2010 Act permits the Minister for Justice to make an order declaring that the Act shall not apply in relation to any "substance, product, preparation, plant, fungus or natural organism" as specified in the order.

The Irish Government's Legislative Programme for Autumn 2026 does not contain any proposed amendments to the above-mentioned legislation which currently govern controlled substances.

The Company has received European Clinical Trial Application approval to initiate the EMBRACE study in Ireland and, as such, will have to abide by the regulations governing clinical trials in Ireland. The CTR is implemented in Ireland via the EU (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 (S.I. No. 99 of 2022), the EU (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022 (S.I. No. 41 of 2022), and the EU (Clinical Trials on Medicinal Products for Human Use) Regulations 2022 (S.I. No. 40 of 2022), (together, the "2022 Regulations").

Clinical trials taking place in Ireland must be conducted in accordance with the CTR, the 2022 Regulations, the Declaration of Helsinki, clinical trial authorization (which has been granted), CT protocol(s), any accompanying documentation relevant to the clinical trial and the conditions and principles of good clinical practice. The manufacturing and importation of an investigational medicinal product in Ireland requires a manufacturer's authorization.

Under the Misuse of Drugs Act 1977 (Controlled Drugs) (Designation) Order 2022 (S.I. No. 211/2022) (the "2022 Order"), as amended most recently by the Misuse of Drugs Act 1977 (Controlled Drugs) (Designation) (Amendment) Order 2026 (S.I. No. 439/2026), controlled drugs enumerated under Schedule 1 of the 2022 Order, including HLP003, can be used for "research, forensic analysis or use as an essential intermediate or starting material in an industrial manufacturing process" once a Ministerial licence under section 14 of the MDA has been obtained. Where the controlled substance is so licensed and the proposed trial is fully compliant with the CTR and the 2022 Regulations, it is possible for a controlled drug designated under Schedule 1 of the 2022 Order, including HLP003, to be used in clinical trials in Ireland.

Under the CTR, the clinical trial sponsor (i.e., the Company) must also upload the clinical trial protocol, the investigator's brochure, the assessment report and any inspection reports to the EU-wide Clinical Trials Information System ("**CTIS**"). Personal and commercially sensitive/confidential information may be redacted from these documents prior to upload as once they are posted to the CTIS they will be publicly available on the CTIS website.

Canada

In Canada, oversight of healthcare is divided between the federal, provincial, and territorial governments. The federal government is responsible for regulating, among other things, the approval, import, sale, and marketing of drugs, including controlled substances and restricted drugs. The provincial and territorial governments have authority over the delivery of health care services, including regulating health facilities, administering health insurance plans such as the Ontario Health Insurance Plan, regulating the distribution and dispensing of prescription drugs, and regulating health professionals such as doctors, psychologists, psychotherapists and nurse practitioners. Regulation of health professionals is generally overseen by various provincial regulatory bodies, such as the College of Physicians and Surgeons of Ontario.

Certain compounds, such as HLP003, are considered controlled substances under Schedule III of the *Controlled Drugs and Substances Act* (Canada) (the "**CDSA**") and restricted drugs under Schedule IV, Part 1 of the *Controlled Substances Regulations* (Canada) (the "**CSR**"). Activities involving such substances, including certain research and clinical trial activities, are subject to the applicable requirements of the CDSA, the CSR and the *Food and Drug Regulations* (Canada) (the "**FDR**"). Depending on the activities being undertaken and the authorizations otherwise available under the applicable regulatory framework, an exemption under section 56 of the CDSA (a "**Section 56 Exemption**") may be required. Section 56 of the CDSA permits the Minister of Health, on such terms and conditions as the Minister considers necessary, to exempt any person or class of persons or any controlled substance or precursor, or any class thereof, from the application of all or any provisions of the CDSA or its regulations if, in the Minister's opinion, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

Health Canada has not approved HLP003 as a drug for any indication. However, there are potential legal routes through which a drug containing HLP003 may be accessed for medical or scientific purposes. These pathways are distinct from authorization to market HLP003 generally in Canada.

Health Canada's Special Access Program ("**SAP**") provides a mechanism through which eligible health or dental practitioners may request access to non-marketed drugs that are not authorized for sale in Canada for the treatment of patients with serious or life-threatening conditions where conventional treatments have failed, are unsuitable or are unavailable in Canada, and where there is sufficient evidence of safety and efficacy for the treatment of the patient's condition. An eligible practitioner may request access through the SAP to a restricted drug that has not been authorized for sale in Canada, subject to the Minister of Health's authorization of the particular request and compliance with applicable regulatory requirements. Access to a restricted drug through the SAP is not equivalent to regulatory approval of a drug for sale in Canada and does not guarantee that the Minister of Health will authorize a particular request. The Company has not sought to facilitate access to HLP003 through the SAP.

The possession, sale and distribution of controlled substances and restricted drugs are subject to the CDSA and applicable regulations, including the CSR and the FDR. Depending on the activity undertaken, authorization may include a dealer's licence, applicable permits, or a Section 56 Exemption. Products that contain a controlled substance, such as HLP003, may only be possessed, produced, imported, exported, sold, provided, transported or otherwise handled to the extent permitted under applicable law and any applicable licence, permit, exemption or other authorization.

Under the CSR, a person may apply to the Minister of Health for a dealer's licence in respect of restricted drugs. A licensed dealer must comply with all the applicable regulatory requirements, including those relating to its facilities and qualified personnel, as well as any terms and conditions imposed on its licence. Subject to the CSR, the terms and conditions of the licence and any applicable permit, a licensed dealer may be authorized to produce, assemble, sell, provide, transport, send, deliver, import or export, or destroy a restricted drug.

The Company intends to sponsor and work with licensed third parties to conduct any clinical trials and research and does not handle controlled substances. If the Company were to conduct this work without the reliance on third parties, it would need to obtain the applicable licences, permits and authorizations described above.

Research and Development

The process required before a prescription drug product candidate may be marketed in Canada generally involves:

- *Chemical and Biological Research* – Laboratory tests are carried out on tissue cultures or with a variety of small animals to determine the effects of the experimental drug. If the results support further development, the manufacturer may proceed to the next step of the drug development process.

- *Preclinical Development* – Animals are given the drug in varying amounts over differing periods of time to study other effects of the drug. If it is demonstrated that the drug causes no serious or unexpected harm at the doses expected to have an effect, the manufacturer will proceed to clinical trials.

- *Clinical Trials – Phase 1* - The first administration in humans is to test if people can tolerate the drug, and to investigate safety, dosage ranges and side-effects. If this testing is to take place in Canada, the manufacturer must prepare and submit a clinical trial application to the Pharmaceutical Drugs Directorate (formerly the Therapeutic Drugs Directorate) (the "**PDD**"). This includes the results of the first two steps and a proposal for testing in humans. If the information meets the applicable requirements, Health Canada may authorize the initiation of clinical testing of the experimental drug, generally first on healthy volunteers.

- *Clinical Trials – Phase 2* - Phase 2 trials are carried out on a larger group of people with the target condition, who are otherwise healthy, with no other medical conditions. Phase 2 trials carried out in Canada must be approved by the PDD. In phase 2, the objective of the trial is to

continue to gather information on the safety of the experimental drug and begin to determine its effectiveness.

- *Clinical Trials – Phase 3* - If the results from phase 2 support further development, the manufacturer provides an updated clinical trial application to the PDD for phase 3 trials. The objectives of phase 3 include determining whether the experimental drug demonstrates effectiveness, and has an acceptable side effect profile, in a very large group of people who better represent the general population. Further information will also be obtained regarding appropriate use of the drug, the optimal dosage and dosing regimen, and the potential adverse effects.

- *New Drug Submission* – If the results from phase 3 support the safety and efficacy of the experimental drug, the drug manufacturer may submit a new drug submission ("**NDS**") to Health Canada. A drug manufacturer may submit an NDS regardless of whether the clinical trials were carried out in Canada. Health Canada reviews all the information gathered during the development of the experimental drug and assesses the safety and efficacy of the drug. If Health Canada determines that, for a specific patient population and specific conditions of use, the benefits of the drug outweigh the known risks, and the applicable requirements of the FDR have been satisfied, Health Canada may authorize the drug for sale in Canada by issuing a Notice of Compliance ("**NOC**").

Compliance with Applicable Laws

The Company oversees and monitors compliance with applicable laws in each jurisdiction in which it operates. In addition to the Company's board of directors ("**Board**") and management responsible for overseeing compliance, the Company has local counsel engaged in every jurisdiction in which it operates and has received legal opinions or advice in each of these jurisdictions regarding (a) compliance with applicable regulatory frameworks, and (b) potential exposure to, and implications arising from, applicable laws in jurisdictions in which the Company has operations or intends to operate.

The Company works with third parties who require regulatory licensing to handle scheduled drugs. The Company continuously updates its compliance and channel programs to maintain regulatory standards set for drug development. The Company also works with clinical research organizations who maintain batch records and data storage for the Company's clinical programs.

Additionally, the Company has established a Medical & Clinical Advisory Team, a Research, Clinical and Regulatory Team and a Government Relations and Communications Team with cross-functional expertise in business, neuroscience, pharmaceuticals, mental health and serotonergic agonists to advise management.

In conjunction with the Company's human resources and operations departments, the Company oversees and implements training on the Company's protocols. The Company expects to continue to work closely with external counsel and other compliance experts, and is evaluating the engagement of one or more independent third party providers to continuously develop, enhance and improve its compliance and risk management and mitigation processes and procedures in furtherance of continued compliance with the laws of the jurisdictions in which the Company operates.

The programs currently in place include monitoring by executives of the Company under the oversight of the Board to ensure that the Company's policies, procedures and operations are appropriately designed to comply with applicable laws, regulations and operating procedures. To the Company's knowledge it is currently in compliance in all material respects with the laws and regulations in all jurisdictions and the related licensing framework applicable to its business activities.

The Company and, to its knowledge, each of its third-party researchers, suppliers and manufacturers have not received any non-compliance, citations or notices of violation which may have an impact on the Company's licences, business activities or operations.

The Company generally conducts due diligence on third-party researchers, medical professionals, clinics, cultivators, processors and others as applicable, with whom it engages. Such due diligence typically includes but is not limited to the review of necessary licenses and the regulatory framework enacted in the jurisdiction of operation. Further, the Company generally obtains, under its contractual arrangements, representations and warranties from such third parties pertaining to compliance with applicable licensing requirements and the regulatory framework enacted in the jurisdiction of operation.

Patent Cooperation Treaty

The PCT facilitates filing for patent recognition in multiple jurisdictions simultaneously using a single uniform patent application. 158 countries, including Canada and the United States have ratified the PCT.

Ultimately, patents are still granted in each country individually. As such, the PCT procedure consists of two phases: filing of an international application, and national evaluation under the patent laws in force in each country where a patent is sought.

Within 12 months of filing a provisional patent application at the USPTO, the Company may elect to file a regular utility patent application in the United States in tandem with filing a PCT application with the World Intellectual Property Office, in each case claiming priority to the provisional patent application. Within 30 months of the provisional filing date, deadlines begin for a PCT application to enter the national phase in desired jurisdictions globally, such as Canada (30 months) and Europe (31 months), in each case claiming priority to the provisional patent application.

While the Company is focused on programs using compounds that are regulated as controlled substances in many jurisdictions, the Company does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates. The Company is exploring drug development within approved laboratory clinical trial settings conducted within approved regulatory frameworks. Though highly speculative, should any prescription drug product be developed by the Company (which, if it does occur, would not be for several years), such drug product will not be commercialized prior to receipt of applicable regulatory approval, which will only be granted if clinical evidence of safety and efficacy for the intended use(s) is successfully developed. The Company may also employ non-prescription drugs, where appropriate.

Selected Quarterly Information

Effective April 1, 2025, the Company changed its presentation currency from the Canadian Dollar to the United States dollar to better reflect the Company's operations, align with the currency in which the majority of cash based expenses are denominated, and improve comparability of its financial results with other publicly traded businesses in the industry. All amounts in the MD&A are therefore presented in USD unless otherwise indicated.

The following table sets forth selected consolidated financial information for the periods indicated that are derived from, and should be read in conjunction with, the Financial Statements and related notes thereto. As a result of the change in reporting currency, the dollar amounts in the table below have been restated from CAD to USD for the periods prior to April 1, 2025. Assets and liabilities at each balance sheet date were translated at the closing rate on those dates. Expense items for prior periods were translated using the average rate for the respective periods.

(United States dollars in thousands, except per share and share figures)	**September 30, 2026**	**June 30, 2026**	**March 31, 2026**	**December 31, 2025**	**September 30, 2025**	**June 30, 2025**	**March 31, 2025**	**December 31, 2024**
Revenues ($)	—	—	—	—	—	—	—	—
Operating Expenses ($)	104,519	49,082	47,579	41,210	28,894	24,624	23,183	22,388
Net loss ($)	(103,091)	(47,819)	(46,995)	(42,668)	(33,722)	(24,613)	(21,307)	(7,539)
Weighted Average Shares - Basic	73,067,021	52,318,151	50,285,080	42,521,329	24,205,871	22,401,197	20,898,038	20,001,406
Loss per share ($)	(1.41)	(0.91)	(0.93)	(1.00)	(1.39)	(1.10)	(1.02)	(0.38)
Weighted Average Shares - Diluted	73,067,021	52,318,151	50,285,080	42,521,329	24,205,871	22,401,197	20,898,038	20,001,406
Loss per share ($)	(1.41)	(0.91)	(0.93)	(1.00)	(1.39)	(1.10)	(1.02)	(0.38)
Cash and cash equivalents	171,071	166,365	157,258	195,128	83,752	118,692	93,922	94,718
Total Assets ($)	263,199	259,655	251,166	290,122	181,246	210,813	179,897	176,208
Total Non-Current Liabilities ($)	926	—	—	—	28,888	44,500	—	—

Assets

Total assets increased by $12,033 from March 31, 2026 to September 30, 2026, mainly as a result of an increase in cash due to the 2026 June Offering (as defined below) and cash raised through the 2026 ATM Program, offset by operating activities. As at September 30, 2026, the Company had prepaid expenses related to future clinical work of $15,284 (March 31, 2026 - $20,289).

Results of Operations

	Three months ended September 30		Six months ended September 30	
(U.S. dollars in thousands)	**2026**	**2025**	**2026**	**2025**
OPERATING EXPENSES				
Research	**30,270**	18,850	**61,031**	33,845
General and administrative costs	**9,288**	9,667	**16,035**	18,543
Share-based compensation	**64,961**	377	**76,535**	1,130
TOTAL OPERATING EXPENSES	**104,519**	28,894	**153,601**	**53,518**
OTHER INCOME				
Interest income	**1,468**	1,065	**2,750**	2,020
Foreign currency translation gain (loss)	**(29)**	(755)	**(48)**	1,189
Other Income (loss)	**(11)**	—	**(11)**	29
Debt issuance costs	**—**	—	**—**	(2,917)
Fair value loss on financial instruments	**—**	(5,138)	**—**	(5,138)
TOTAL OTHER INCOME (EXPENSE)	**1,428**	(4,828)	**2,691**	(4,817)
NET LOSS FOR THE PERIOD	**103,091**	33,722	**150,910**	58,335
Basic loss per share for the period	**1.41**	1.39	**2.40**	2.50
Weighted average number of common shares outstanding - basic	**73,067,021**	24,205,871	**62,749,278**	23,308,465

For the three and six month periods ended September 30, 2026, Helus Pharma incurred a net loss of $103,091 and $150,910 respectively compared to a net loss of $33,722 and $58,335 during the same periods in prior year. The net loss for the three and six months ended September 30, 2026, includes a non-cash component related to share-based compensation of $64,961 and $76,535 respectively, compared to $377 and $1,130 during the same periods in prior year. The significant increase in share-based compensation was primarily attributable to several equity compensation events during the quarter, including the acceleration of vesting of certain outstanding RSUs, resulting in the recognition of $15,425 of previously unrecognized share-based compensation expense, immediately vested RSU awards, and new RSU and PSU grants.

During the three and six months ended September 30, 2026, the Company was focused on progressing its various research programs, with a focus on its HLP003 Program. The APPROACH trial completed enrollment in July 2026 while enrollment in the EMBRACE trial and activities related to the EXTEND study remained ongoing. The HLP004 program also continued to advance, with the Company completing the design of the next HLP004 study. In addition, both the HLP003 and the HLP004 clinical programs progressed towards the milestones noted above. See "*Non-Revenue Generating Projects*".

Operating expenses

For the three month period ended September 30, 2026, operating expenses totaled $104,519 (2025 - $28,894). The operating expenses include a non-cash component of $64,961 (2025 - $377) related to share-based compensation. Operating expenses excluding share-based compensation were $39,558 (2025 – $28,517). The operating expenses were incurred to support research activities, financing activities, and the overall development and growth of the Company. See below for further discussion of the changes in operating expenses between the periods.

For the six month period ended September 30, 2026, operating expenses totaled $153,601 (2025 - $53,518). The operating expenses include a non-cash component of $76,535 (2025 - $1,130) related to share-based compensation. Operating expenses excluding share-based compensation were $77,066 (2025 – $52,388). The operating expenses were incurred to support research activities, financing activities, and the overall development and growth of the Company. See below for further discussion of the changes in operating expenses between the periods.

Operating expenses excluding share-based compensation is a non-IFRS financial measure. The Company considers certain non-IFRS measures to be meaningful indicators of the performance of its business. These measures do not have a standardized meaning under IFRS Accounting Standards and may not be comparable to (and may be calculated differently by) other companies that present similar measures. Accordingly, these measures should not be considered in isolation from nor as a substitute for the Company's financial information reported under IFRS. Operating expenses excluding share-based compensation is calculated as operating expenses less share-based compensation. The Company believes this measure provides investors with useful supplemental information regarding the operating performance of the Company's business.

Research

For the three month period ended September 30, 2026, the Company's research expenses totaled $30,270 compared to $18,850 during the same period in the prior year. Research expenses primarily consisted of costs associated with the advancement of the development programs of $25,197 (2025 - $15,192) and payroll related expenses of $4,321 (2025 - $3,016).

For the six month period ended September 30, 2026, the Company's research expenses totaled $61,031 compared to $33,845 during the same period in the prior year. Research expenses primarily consisted of costs associated with the advancement of the development programs of $50,486 (2025 - $27,287) and payroll related expenses of $8,527 (2025 - $5,612).

The increases in research expenses for the three and six month periods ended September 30, 2026 were primarily attributable to increased expenditures associated with the continued advancement of the Company's clinical development programs, particularly the HLP003 Phase 3 clinical trials. The PARADIGM trials progressed throughout the periods, with the APPROACH trial completing enrollment in July 2026, while enrollment in the EMBRACE trial and activities related to the EXTEND study remained ongoing. The Company also continued to advance the HLP004 program, including completion of the design of the next HLP004 study. Refer to *Non-Revenue Generating Projects* for additional information on the advancement of the Company's proprietary clinical programs.

General and Administration Costs

For the three month period ended September 30, 2026, general and administrative expenses were $9,288 compared to $9,667 during the same period in the prior year. General and administrative expenses primarily consisted of investor relations and marketing media of $3,179 (2025 - $349), payroll and benefits of $2,258 (2025 - $3,097) professional and consulting fees of $1,492 (2025 - $969), office and administration expenses of $1,303 (2025 - $936), and capital markets expenses $750 (2025 - $3,833). The decrease in general and administrative expenses was primarily attributable to lower capital markets expenses and payroll and benefits, partially offset by higher investor relations and marketing media expenses, professional and consulting fees, and office and administration expenses.

For the six month period ended September 30, 2026, general and administrative expenses were $16,035 compared to $18,543 during the same period in the prior year. General and administrative expenses primarily consisted of payroll and benefits of $5,272 (2025 - $4,704), investor relations and marketing media of $4,495 (2025 - $730), professional and consulting fees of $2,689 (2025 - $3,877), office and administration expenses of $2,356 (2025 - $1,706), and capital markets expenses $895 (2025 - $6,492). The decrease in general and administrative expenses was primarily attributable to lower capital markets expenses and professional and consulting fees, partially offset by higher investor relations and marketing media expenses, payroll and benefits, and office and administration expenses.

Share-Based Compensation

For the three and six month periods ended September 30, 2026 , the Company recorded a share-based compensation expense of $64,961 and $76,535 respectively compared to $377 and $1,130 during the same periods in prior year. The significant increase in share-based compensation was primarily attributable to several equity compensation events during the quarter, including the acceleration of vesting of certain outstanding RSUs, resulting in the recognition of $15,425 of previously unrecognized share-based compensation expense, and new RSU and PSU grants. See note 7, *Share Capital* in the Financial Statements for additional details on the equity instruments granted during the three and six month periods.

The share-based compensation expense related to options and warrants granted was recorded based on the fair value using a Black Scholes Model. On exercise of warrants and options the equity reserve balances will be moved to share capital. The share-based compensation expense related to RSUs was recorded based on the grant-date fair value of the underlying Common Shares. In the absence of transfer restrictions, grant-date fair value is generally based on the closing price of the Common Shares on the grant date. Where RSUs or the underlying Common Shares are subject to substantive contractual lock-up, transfer, or resale restrictions, grant-date fair value may be adjusted to reflect the impact of those restrictions on the holder's ability to sell, monetize, diversify, or hedge the shares. Grant-date fair value reflects market-based vesting conditions, if applicable, but excludes the effect of non-market performance and service vesting conditions. Upon issuance of Common Shares on vested RSUs, the related amounts are transferred from the RSU reserve to share capital. The share-based compensation expense related to PSUs was determined based on the Monte Carlo simulation valuation model. This model incorporates assumptions including the Company's share price at the grant date, expected share price volatility, and the probability of achieving the market-based

performance conditions over the term of the award. Upon issuance of Common Shares on vested PSUs, the related amounts are transferred from the PSU reserve to share capital.

Other Income

Foreign Currency Translation Gain (Loss)

For the three month period ended September 30, 2026, the Company incurred a foreign currency translation loss from operations and revaluations of balance sheet assets and liabilities held in foreign currencies of $29. The Company holds assets and liabilities in Canadian dollars, United States dollars, Euros, and British pounds.

For the six month period ended September 30, 2026, the Company incurred a foreign currency translation loss from operations and revaluations of balance sheet assets and liabilities held in foreign currencies of $48. The Company holds assets and liabilities in Canadian dollars, United States dollars, Euros, and British pounds.

Interest Income

For the three and six month periods ended September 30, 2026 the Company recorded interest income of $1,468 and $2,750, respectively compared to $1,065 and $2,020 during the same periods in prior year. The Company earns interest on certain cash balances, and the resulting interest income will fluctuate in line with both the level of average interest-bearing cash and movements in market interest rates.

Liquidity, Capital Resources and Cash Flows

	Three months ended September 30,		**Change**		**Six months ended September 30,**		**Change**	
(U.S. dollars in thousands)	**2026**	**2025**	**$**	**%**	2026	**2025**	**$**	**%**
Net cash used in operating activities	**(35,303)**	(34,485)	(818)	2 %	**(72,373)**	(64,033)	(8,340)	13 %
Net cash used in investing activities	**(363)**	(436)	73	(17)%	**(683)**	(657)	(26)	4 %
Net cash flows provided by financing activities	**40,417**	27	40,390	149593 %	**86,950**	54,660	32,290	59 %
Increase in cash	**4,751**	(34,894)	39,645	(114)%	**13,894**	(10,030)	23,924	(239)%
Net foreign exchange difference	**(45)**	(46)	1	(2)%	**(81)**	(140)	59	(42)%
Cash and cash equivalents, beginning of period	**166,365**	118,692	47,673	40 %	**157,258**	93,922	63,336	67 %
Cash and cash equivalents, end of period	**171,071**	83,752	87,319	104 %	**171,071**	83,752	87,319	104 %

Net cash used in operating activities	Primarily relates to cash used for operating expenses including research expenses, salaries, and other general and administration expenses. Cash flows from operating activities exclude expenses not affecting cash, such as share based compensation expense, depreciation and amortization, unrealized foreign exchange gains or losses, lease interest accretion and net changes in non-cash balances relating to operations.	
	For the three months ended September 30, 2026, cash used in operating activities was $35,303 driven by a net loss for the period of $103,091 partially offset by a decrease in working capital of $2,735, and by the following non-cash items: share-based compensation of $64,961, depreciation and amortization of $52, a non cash unrealized foreign exchange loss of $29 and lease interest accretion of $11.	For the six months ended September 30, 2026, cash used in operating activities was $72,373 driven by a net loss for the period of $150,910, partially offset by a decrease in working capital of $1,860, and by the following non-cash items: share-based compensation of $76,535, depreciation and amortization of $83, a non-cash unrealized foreign exchange loss of $48 and lease interest accretion of $11.
Net cash used in investing activities	For the three months ended September 30, 2026, cash used in investing activities was driven by the purchase of equipment and intangible assets of $363.	For the six months ended September 30, 2026, cash used in investing activities was driven by the purchase of equipment and intangible assets of $683.
Net cash provided by financing activities	For the three months ended September 30, 2026, cash from financing activities was $40,417 driven by net cash received from the issuance of Common Shares net of issuance costs of $39,880, proceeds from warrants exercised $1,539, partially offset by taxes paid related to net share settlement of RSUs of $995, and lease interest payment of $7.	For the six months ended September 30, 2026, cash from financing activities was $86,950 driven by the net cash received from the issuance of Common Shares net of issuance costs of $86,413, proceeds from exercise of warrants of $1,539 partially offset by taxes paid related to net share settlement of RSUs $995 and lease interest payment of $7.

LPC Agreement

On May 30, 2023, the Company entered into a Common Share purchase agreement (the "**LPC Purchase Agreement**") with Lincoln Park Capital Fund, LLC. The LPC Purchase Agreement terminated automatically in accordance with its terms on or about June 1, 2026, upon the expiry of its 36-month term.

Base Shelf Prospectus

On September 17, 2025, the Company filed the 2025 Base Shelf Prospectus in each of the provinces and territories of Canada. The 2025 Base Shelf Prospectus qualifies for distribution, from time to time during the 25-month period from the date of the 2025 Base Shelf Prospectus, of up to C$1,700,000 in the aggregate of Common Shares, warrants, units, debt securities and subscription receipts of the Company.

In determining that the Company has a reasonable expectation to distribute, during the 25-month period that the 2025 Base Shelf Prospectus, including any amendments thereto, remains valid, up to C$1,700,000 in the aggregate of securities, management of the Company considered its ongoing

contractual commitments and amounts qualified under prospectus supplements to the Company's registration statement on Form F-10, as amended (File No. 333-289139).

As of the date hereof, the Company has approximately C$842,200 available under the 2025 Base Shelf Prospectus, which management of the Company reasonably expects to distribute during the 25-month period that the 2025 Base Shelf Prospectus, including any amendments thereto, remains valid.[27]

The Company believes that the size of the 2025 Base Shelf Prospectus is reasonable having regard to its current liquidity position, working capital of $177,060 as at September 30, 2026, cash balance of $171,071, its anticipated cash needs over the next 12–24 months (see "Non-Revenue Generating Projects") and its historical and expected access to the public capital markets. The Company's future funding strategy contemplates continued access to both public and private sources of capital as required to advance its non-revenue-generating research and development programs, fund capital expenditures and meet ongoing operating obligations. The Company will continue to assess, on a prospective basis, its liquidity, capital resources and market conditions to ensure that the total amount of securities qualified under its base shelf prospectus remains appropriate in relation to its business, growth plans and financial condition.

Registered Direct Offering

On October 31, 2025, the Company completed a registered direct offering of 22,277,750 Common Shares and, in lieu of Common Shares to certain investors, 4,605,500 pre-funded Common Share purchase warrants (the "**Pre-Funded Warrant**") at a price of $6.51 per Common Share or Pre-Funded Warrant for aggregate gross proceeds of approximately $175,010 (the "**Registered Direct Offering**"). Common Share issuance costs related to the Registered Direct Offering were $10,992, of which $9,109 was allocated to Common Shares and $1,883 allocated to the Pre-Funded Warrants.

Each Pre-Funded Warrant entitles the holder thereof to acquire one Common Share at a nominal exercise price. The Pre-Funded Warrants do not expire.

Each Common Share and each Pre-Funded Warrant is accompanied by 0.35 of one Common Share purchase warrant (each whole warrant, a "Warrant" and together with the Common Shares and Pre-Funded Warrants, the "**Offered Securities**"). Each Warrant is exercisable to acquire one Common Share at a price of $8.14 per Common Share at any time prior to the earlier of: (i) June 30, 2027; (ii) thirty days following the publication by press release of topline data for the APPROACH trial of HLP003 in major depressive disorder; and (iii) thirty days following the date a press release is issued by the Company announcing exercise of its acceleration right, which right can only be exercised if the closing price of the Common Share on the Nasdaq is equal to or exceeds $19.53 per Common Share for any five consecutive trading days. The Company used a portion of the net proceeds from the Registered Direct Offering to repay the outstanding Convertible Debentures, and intends to use the remaining net proceeds to progress the Company's HLP003, HLP004, and HLP005 programs, and for working capital and general corporate purposes.

[27] This is a forward-looking statement that involves material assumptions by the Company. There is no certainty as to the Company's ability to distribute securities or to raise additional funding to support operations. See "*Risk Factors*".

During the six month period ended September 30, 2026, 3,040,250 Pre-Funded Warrants were converted into 3,040,242 Common Shares of the Company. As at September 30, 2026, all 4,605,500 Pre-Funded Warrants have been converted into 4,605,488 Common Shares of the Company, with no Pre-Funded Warrants remaining outstanding.

2026 ATM Program

On December 30, 2025, the Company established a new at-the-market equity program (the "**2026 ATM Program**") that allows the Company to issue and sell up to $100,000 of Common Shares from treasury to the public, from time to time. Distributions of Common Shares under the 2026 ATM Program are made pursuant to the terms and conditions of an at-the-market equity distribution agreement (the "**2026 Distribution Agreement**") dated December 30, 2025, among the Company, Cantor Fitzgerald Canada Corporation and Cantor Fitzgerald & Co. The 2026 ATM Program is to be effective until the earlier of the issuance and sale of all of the Common Shares issuable pursuant to the 2026 ATM Program and October 17, 2027, unless earlier terminated in accordance with the terms of the 2026 Distribution Agreement. As at September 30, 2026, the Company has sold 3,100,000 shares under the 2026 ATM Program, at an average price of $13.30 per Common Share, for aggregate gross proceeds of $41,230. Common Share issuance costs related to the 2026 ATM Program are $1,493, of which $1,288 was incurred during the six month period ended September 30, 2026.

June 2026 Underwritten Offering

On June 25, 2026, the Company completed an underwritten offering of 10,309,280 Common Shares at an offering price of $4.85 per Common Share, for aggregate gross proceeds of $50,000 (the "**2026 June Offering**"), pursuant to an underwriting agreement dated June 23, 2026, between the Company and Cantor Fitzgerald & Co., Barclays Capital Inc., Bloom Burton Securities Inc., and Lucid Capital Markets. The Company intends to use the net proceeds from the Offering to progress the Company's HLP003 for MDD with Phase 3 APPROACH data expected in the fourth quarter of 2026, HLP004 for generalized anxiety disorder, and HLP005 programs, and for working capital and general corporate purposes. In consideration for their services, the Company paid to the underwriters a cash commission of $3,000 and incurred additional share issuance costs, being professional fees of $529.

Overview

The Company's main use for liquidity is to fund the development of its research programs as noted above. The primary source of liquidity has been from public financing to date. The ability to fund operations, to make planned capital expenditures and execute the growth/acquisition strategy depends on the future operating performance and cash flows, which are subject to prevailing economic conditions, regulatory and financial, business and other factors, some of which are beyond the Company's control.

As at September 30, 2026 the Company had working capital of $177,060. The Company is in the clinical development stage and has not commercialized any products to date. Therefore the Company will not be able to generate sufficient amounts of cash and cash equivalents from its operations in the short term.

The Company intends to continue to advance its non-revenue generating programs over the next twelve to twenty-four months. These intended advancements, along with the expectation of operating at a loss for at minimum the next 12 months, will diminish the Company's working capital. As such, further financings are expected to be required to develop the Company's pipeline, make acquisitions, meet ongoing obligations, and discharge its liabilities in the normal course of business. There is no assurance that additional funds can be raised upon terms acceptable to the Company, or at all, as funding for small companies remains challenging.

The Company's ability to access both public and private capital is dependent upon, among other things, general market conditions and the capital markets generally, market perceptions about the Company and its business operations, and the trading prices of the Company's securities from time to time. When additional capital is required, the Company intends to raise funds through the issuance of equity or equity-linked securities or the incurrence of debt. Other possible sources include the exercise of stock options and warrants of the Company. There can be no assurance that additional funds can be raised upon terms acceptable to the Company, or at all, as funding for early-stage companies remains challenging generally. Given the nature of the Company's business, and in particular, the fact that its operations are conducted legally through licensed third parties exclusively within foreign jurisdictions, the Company may face difficulty in accessing traditional sources of financing.

The Company's current expenditure obligations include commitments for those projects described in the section entitled "*Non-Revenue Generating Projects*" in this MD&A. The Company expects to continue funding these projects with available cash and cash equivalents, and therefore, is subject to risks including, but not limited to, an inability to raise additional funds through debt and/or equity financing to support the Company's continued development, including capital expenditure requirements, operating requirements and to meet its liabilities and commitments as they become due.

The Company constantly monitors and manages its capital resources to assess the liquidity necessary to fund operations and capacity expansion. As at September 30, 2026, the Company had a cash balance of $171,071 and current liabilities of $17,886. The Company's current resources are sufficient to settle its current liabilities.

Management continues to raise the capital necessary to become a fully operational enterprise.

The Company has negative cash flow from operating activities and has historically incurred net losses. To the extent that the Company has negative operating cash flows in future periods, it may need to deploy a portion of its existing working capital to fund such negative cash flows. The Company will be required to raise additional funds through the issuance of additional equity securities, through loan financing, or other means, such as through partnerships with other companies and research and development reimbursements. There is no assurance that additional capital or other types of financing will be available if needed or that these financings will be on terms at least as favorable to the Company as those previously obtained.

The Company's primary capital needs are funds to advance its research and development activities and for working capital purposes. These activities include staffing, preclinical studies, clinical trials and administrative costs. The Company has experienced operating losses and cash outflows from operations since incorporation and will require ongoing financing to continue its research and

development. The Company has not earned any revenue or reached successful commercialization of any products. The Company's success is dependent upon the ability to finance its cash requirements to continue its activities. There is no assurance that additional capital or other types of financing will be available if needed or that these financings will be on terms at least as favorable to the Company as those previously obtained, or at all. See "*Risk Factors"*.

The Company is focused on research and has not seen any major changes to its ability to complete those activities. The Company intends to assess its business and operational needs, and implement cost reductions as needed. The Company is currently focused on the research stage of its projects and will not be generating significant revenues in the short term. The Company believes it has sufficient working capital to manage its short- and long-term cash flow needs as it continues to invest into its intellectual property.

Contractual Obligations and Commitments

As at September 30, 2026, the Company had also entered into agreements for various studies which may require the Company to spend up to an additional $84,787. The Company expects to pay this amount within the next 24 months, however the timing and certainty of the payments are contingent on availability of materials and successful completion of certain milestones. The Company has the right to cancel the studies at its discretion, in which case a cancellation fee may apply, however the Company is not liable to pay the full amount of the study.

In addition to the above, the Company has entered into an exclusive license agreement with Mindset to acquire an extensive targeted class of tryptamine-based molecules. Upon the successful completion of certain milestones contemplated in the agreement, the Company may have to pay additional consideration of up to $9,500. At the sole discretion of Helus Pharma, the milestones may be paid in cash or in Common Shares, or a combination thereof, subject to the approval of Cboe Canada. There is no assurance that the aforementioned milestones will be met.

The Company is party to certain employee and management contracts that contain severance obligations. These contracts contain clauses requiring additional payments to be made upon the occurrence of involuntary termination. As the likelihood of these events taking place is not determinable, no contingent liabilities have been recorded in the consolidated financial statements.

As of September 30, 2026, no material litigation or class proceedings have been commenced or certified. Should any litigation or class actions that the Company becomes involved in be unable to be resolved favorably or if any claims or litigation are determined against the Company, the Company's financial position, operating results and the trading price of the Common Shares could be materially adversely affected.

In the normal course of business, the Company may be subject to legal proceedings and claims. As at September 30, 2026, there was no material ongoing litigation and therefore no contingent liabilities have been recorded.

The Company is not aware of any legal proceedings or claims that would reasonably be expected to have a materially adverse effect on its business, financial condition or results of operations.

Outstanding Share Data

On September 19, 2024, the Company completed the Consolidation. As a result, all figures related to shares, warrants, options, restricted share units, performance share units and earnings per share presented in this MD&A have been restated retrospectively for all periods to reflect the Consolidation.

The table below sets out the outstanding share capital of the Company as at September 30, 2026, and as of the date of this MD&A:

Class of Security	As of September 30, 2026	As of the date of this MD&A
Common Shares	79,550,749	79,807,667
Stock options	825,935	825,935
RSUs	2,235,803	2,194,135
PSUs	283,334	283,334
Common Share purchase warrants	12,016,335	11,801,085

Common Shares

The authorized capital of the Company consists of an unlimited number of Common Shares without par value and an unlimited number of preferred shares. As of September 30, 2026, 79,550,749 Common Shares were outstanding and no preferred shares were issued and outstanding. As of the date of this MD&A 79,807,667 Common Shares were outstanding and no preferred shares were issued and outstanding.

Stock Options

As of September 30, 2026, options to purchase up to 825,935 Common Shares were outstanding under Helus Pharma's equity incentive plan. As of the date of this MD&A, options to purchase up to 825,935 Common Shares are outstanding under Helus Pharma's equity incentive plan.

Restricted Share Units

As of September 30, 2026, 2,235,803 RSUs were outstanding, of which 1,265,803 were issued under Helus Pharma's equity incentive plan, and 970,000 were issued outside of the equity incentive plan. As of the date of this MD&A, 2,194,135 RSUs are outstanding, of which 1,224,135 were issued under Helus Pharma's equity incentive plan, and 970,000 were issued outside of the equity incentive plan. Furthermore, as of the date of this MD&A, the Company has the obligation to grant 34,440 RSUs to certain directors and former officers of the Company pursuant to contractual arrangements. See "*Subsequent Events*".

Performance Share Units

As of September 30, 2026, and as of the date of this MD&A, 283,334 performance share units ("**PSUs**") were outstanding. The PSUs were issued outside of Helus Pharma's equity incentive plan.

Common Share Purchase Warrants

As of September 30, 2026, warrants to purchase up to 12,016,335 Common Shares were outstanding, exercisable at a weighted average exercise price of $10.14 per Common Share. As of the date of this MD&A, warrants to purchase up to 11,801,085 Common Shares were outstanding, exercisable at a weighted average exercise price of $10.14 per Common Share.

Off-Balance Sheet Arrangements

As at September 30, 2026, and the date of this MD&A, other than those contractual obligations and commitments disclosed in note 11 of the Financial Statements, the Company does not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the results of operations or financial condition of the Company.

Transactions Between Related Parties

As at the date of this MD&A, key management personnel of the Company consists of the Board, Chief Executive Officer, Chief Financial Officer and Chief Medical Officer. During the three and six month periods key management personnel also consisted of the President, Chief Growth Officer, Chief Legal Officer, Chief Operating Officer, and Chief Business Officer.

Compensation for key management personnel of the Company for the three and six month periods ended September 30, 2026, consisted of payroll, consulting fees, short term benefits and other compensation of $62,067 and $75,330 respectively (three and six month periods ended September 30, 2025 - $2,218 and $3,447)

The Board formed a committee to conduct a formal search for a Chief Executive Officer to guide the Company through its next phase of growth and clinical advancement. On February 10, 2026, the Company announced the appointment of Michael Cola as Chief Executive Officer, effective immediately. Michael Cola served as Chief Executive Officer from February 10, 2026 to April 20, 2026. The Board appointed Co-founder and Executive Chairman Eric So to resume his role as Interim Chief Executive Officer for a short period of time while a search was conducted for a successor. On August 3, 2026, the Company appointed Michael Halstead as Chief Executive Officer of the Company.

On September 26, 2025, the Board authorized the Company to enter into amended consulting agreements with the Company's President and Interim Chief Executive Officer, Eric So, and Chief Growth Officer, Paul Glavine (each, an "**Executive**"), through their respective consulting corporation, pursuant to which each Executive would be entitled to receive, subject to the approval of the Board and the terms of the Helus Pharma's equity incentive plan, performance-based awards within the available equity pool or cash payments in lieu thereof. The number of awards that may be granted is determined by reference to specified performance criteria established by the Board, including the completion by the Company of an equity or convertible debt financing or series of equity or convertible debt financings totaling a minimum of C$75 million during the period commencing on September 26, 2025, and ending on December 31, 2026. Subject to satisfaction of the applicable performance criteria, each of the Executives is entitled to receive awards equal to 40% of the space made available under Helus Pharma's equity incentive plan by such financing. Such performance

awards were originally scheduled to vest into Common Shares over a three-year period following the grant date; however, such vesting schedule was accelerated pursuant to the terms of the amended consulting agreements upon the achievement of a five-day volume weighted average trading price of the Common Shares on Cboe Canada equal to or greater than a 40% premium to the closing price of the Common Shares on October 31, 2025. All performance awards granted pursuant to the amended consulting agreements have vested and any performance awards that the Company may be obligated to grant in future pursuant to the amended consulting agreements will vest immediately. On October 26, 2026, the Company terminated the consulting agreements and employment agreements with the Executives (See "*Subsequent Events*"). In connection with the termination, the Company paid Eric So cash consideration of $2,416 and paid Paul Glavine cash consideration of $2,376 pursuant to the terms of the employment agreements. Pursuant to the terms of the amended consulting agreements, the obligation to grant performance awards to the Executives survives termination of the amended consulting agreements in respect of any equity or convertible debt financing completed on or before December 31, 2026. As of the date of this MD&A, each Executive has received 3,238,519 Common Shares and is currently entitled to an additional 17,220 Common Shares.

Shareholder Rights Plan

The Board has adopted a shareholder rights plan (the "**Rights Plan**") to ensure, to the extent possible, that all shareholders of the Company and the Board have adequate time to consider and evaluate any unsolicited take-over bid for the Company, provide the Board with adequate time to evaluate any such take-over bid and explore and develop value-enhancing alternatives to any such take-over bid, encourage the fair treatment of the Company's shareholders in connection with any such take-over bid, and generally assist the Board in enhancing shareholder value. The Rights Plan was approved by the Company's shareholders on, and took effect as of, August 16, 2021. An amended and restated Rights Plan was approved by shareholders at the Company's annual and special meeting of shareholders held on August 27, 2024.

Critical Accounting Estimates

The preparation of the Financial Statements requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual outcomes could differ from these estimates. The Financial Statements include estimates which, by their nature, are uncertain. The impacts of such estimates are pervasive throughout the Financial Statements and may require accounting adjustments based on future occurrences. Revisions to accounting estimates are recognized in the period in which the estimate is revised and future periods if the revision affects both current and future periods. These estimates are based on historical experience, current and future economic conditions and other factors, including expectations of future events that are believed to be reasonable under the circumstances. The Company's significant accounting estimates and assumptions are reported in note 2 of the Financial Statements and in note 3 of the Company's annual consolidated financial statements for the year ended March 31, 2026 found on SEDAR+ at www.sedarplus.ca.

Summary of Significant Accounting Policies

The Company's significant accounting policies are set out in note 2 of the Company's annual consolidated financial statements for the year ended March 31, 2026, found on SEDAR+ at *www.sedarplus.ca*. This MD&A should be read in conjunction with the Financial Statements. Other accounting standards or amendments to existing accounting standards that have been issued, but have future effective dates, are either not applicable or are not expected to have a significant impact on the Financial Statements.

Disclosure Controls and Procedures

Management maintains appropriate information systems, procedures and controls to provide reasonable assurance that information that is publicly disclosed is complete, reliable and timely. The Chief Executive Officer (the "**CEO**") and Chief Financial Officer (the "**CFO**") of the Company, along with the assistance of senior management under their supervision, have designed disclosure controls and procedures to provide reasonable assurance that material information relating to the Company is made known to the CEO and CFO, and have designed internal controls over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS.

Internal Control Over Financial Reporting

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with applicable IFRS. Internal control over financial reporting should include those policies and procedures that establish the following:

- maintenance of records in reasonable detail, that accurately and fairly reflect the transactions and dispositions of assets;
- reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with applicable IFRS;
- receipts and expenditures are only being made in accordance with authorizations of management or the Board; and
- reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial instruments.

During the period ended September 30, 2026, the Company did not make any significant changes to its internal controls over financial reporting that would have materially affected, or reasonably likely to materially affect, its internal controls over financial reporting.

Limitations of Disclosure Controls and Procedures and Internal Control Over Financial Reporting

The Company's management, including the CEO and the CFO, believe that due to inherent limitations, any disclosure controls and procedures or internal control over financial reporting, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. These inherent limitations include, among other items: (i) that management's assumptions and judgments could ultimately prove to be incorrect under varying conditions and circumstances; (ii) the impact of any undetected errors; and (iii) that controls may be circumvented by the unauthorized acts of individuals, by collusion of two or more people, or by management override. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Accordingly, because of the inherent limitations in a cost effective control system, misstatements due to error or fraud may occur and not be detected.

New standards and interpretations

IFRS 9, Financial Instruments ("IFRS 9") and IFRS 7, Financial Instruments: Disclosures ("IFRS 7")

In May 2024, the IASB issued targeted amendments to IFRS 9 and IFRS 7 in response to practical implementation issues and to introduce new requirements applicable to both financial institutions and corporate entities. These amendments aim to enhance the clarity and consistency of financial reporting for various types of financial instruments and their related disclosures by (i) clarifying the date of recognition and derecognition for certain financial assets and liabilities, including a new exception for financial liabilities settled through an electronic cash transfer system (ii) providing help to determine whether a financial asset meets the Solely Payments of Principal and Interest criterion (iii) introducing new disclosures for instruments with contractual terms that may alter cash flows, such as financial instruments linked to the achievement of environmental, social, and governance targets, and (iv) updating the disclosure requirements for equity instruments designated at fair value through other comprehensive income. The new standard is to be effective for annual periods beginning on or after January 1, 2026. The Company has determined that adoption of these amendments has no significant effect on the Company's consolidated financial statements.

New standards and interpretations not yet adopted

IFRS 18, Presentation and Disclosure in Financial Statements

In April 2024, the IASB issued IFRS 18 that is to replace IAS 1, Presentation of Financial Statements. The new standard aims to improve the quality of financial reporting by: (i) requiring defined subtotals in the statement of profit or loss; (ii) requiring disclosure about management defined performance measures; and (iii) adding new principles for aggregation and disaggregation of information. The standard is effective for the annual reporting periods beginning on or after January 1, 2027, with early application permitted. The Company is in the process of assessing the impact of this new standard on its consolidated financial statements.

All other IFRSs and amendments issued but not yet effective have been assessed by the Company and are not expected to have a material impact on the Company's consolidated financial statements.

Financial and Risk Management

The Company is exposed to a variety of financial instrument related risks and is exposed to liquidity risk, credit risk, interest rate risk, foreign exchange risk, equity price risk, asset forfeiture risk and banking risk. Management, in conjunction with the Board, mitigates these risks by assessing, monitoring and approving the Company's risk management processes. See note 14, *Financial Instruments* in the Financial Statements for the Company's financial instruments, financial risk factors, and other instruments. The Company's financial risk activities are governed by the appropriate policy and procedures and financial risks are identified, measured and managed in accordance with the Company's policies and risk appetite.

In addition, the Company noted the following risks specific to the pharmaceutical industry that it is exposed to:

Liquidity Risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company is a development stage company and is reliant on external fundraising to support its operations. Once funds have been raised, the Company manages liquidity risk by continuously monitoring actual and projected cash flows. The Board reviews and approves the Company's operating and capital budgets, as well as any material transactions not in the ordinary course of business.

Regulatory Risk

Regulatory risk pertains to the risk that the Company's business objectives are contingent, in part, upon the compliance with regulatory requirements. Due to the nature of the industry, regulatory requirements can be more stringent than other industries and may also be punitive in nature. Any delays in obtaining, or failure to obtain regulatory approvals can significantly delay operational and product development and can have a material adverse effect on the Company's business, results of operation, and financial condition.

The Company routinely monitors regulatory changes occurring in the regulation of serotonergic agonists as controlled substances at the city, state, and national levels as it relates to the pharmaceutical industry. Unforeseen regulatory changes could have a material adverse effect on the business as a whole.

Currency Risk

The Company is exposed to currency risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. Currency risk is limited to the portion of the Company's business transactions and balances denominated in currencies other than the United States dollar.

Subsequent Events

Effective October 1, 2026, the Company's legal name changed from Cybin Inc. to Helus Pharma Inc. The name change was approved by shareholders at the Company's annual and special meeting of shareholders held on September 22, 2026. The name change follows the Company's adoption of the business name "Helus Pharma" on January 5, 2026. The name change had no impact on the Company's financial position, results of operations or cash flows.

On October 2, 2026, the vesting of 41,668 RSUs was accelerated, resulting in these RSUs immediately vesting.

On October 6, 2026, 215,250 Warrants were exercised and converted into 215,250 Common Shares for gross proceeds of $1,752.

On October 6, 2026, the Company was obligated to issue 34,440 RSUs to certain directors and former officers of the Company pursuant to contractual arrangements.

On October 15, 2026, the Company announced the appointment of Suresh Durgam, M.D., to the Board. Dr. Durgam previously served on the Company's Scientific Advisory Board.

On October 21, 2026, the Company announced that its HLP004 Program is progressing with Phase 2 monotherapy study for the potential treatment of GAD. The study will be a multi-center, randomized, double-blind, placebo-controlled study, evaluating the efficacy and safety of two 30 mg administrations three weeks apart of HLP004 monotherapy versus inactive placebo in adult patients with GAD. The study will enroll adult participants using the Diagnostic and Statistical Manual of Mental Disorders fifth edition primary diagnosis of GAD, who have a minimum Hamilton Anxiety Rating Scale ("HAM-A") total score of $\geq$ 20 at screening and baseline. Approximately 144 participants will be randomized in a 1:1 ratio to either 30 mg of HLP004 or inactive placebo. The primary endpoint and key secondary endpoint are change from baseline in HAM-A total score at Week 6 and Week 12, respectively.

On October 27, 2026, the Company announced that Eric So and Paul Glavine had stepped down from their executive and consulting roles with the Company, effective October 26, 2026, but will continue to serve on the Board. Pursuant to the terms of those consulting and employment agreements, the Company agreed to pay the former executives an aggregate of $4,792 in connection with the termination of the agreements.

RISK FACTORS

In addition to the risks described herein, reference is made to the section entitled "*Risk Factors*" in the AIF, which is incorporated herein by reference. The business, financial condition, revenues or profitability of the Company could be materially adversely affected by any of the risks set forth in this MD&A. The trading price of the Common Shares could decline due to any of these risks and investors could lose all or part of their investment. This MD&A contains forward-looking statements that involve risks and uncertainties. The Company's actual results could differ materially from those

anticipated in these forward-looking statements as a result of certain factors, including the risks faced by the Company described below and elsewhere in this MD&A.

Risks Related to the Company's Business and Industry

Limited Operating History

The Common Shares commenced trading on Cboe Canada on November 10, 2020 on a post-reverse takeover basis and therefore the Company has a limited operating history as a public company. To operate effectively, the Company will be required to continue to implement changes in certain aspects of its business, improve information systems and develop, manage and train management-level and other employees to comply with ongoing public company requirements. Failure to take such actions, or delay in implementation thereof, could adversely affect the business, financial condition, liquidity and results of operations of the Company and, more specifically, could result in regulatory penalties, market criticism or the imposition of cease trade orders in respect of the Common Shares.

The Company will be subject to all of the business risks and uncertainties associated with any new business enterprise, including the risk that it will not achieve its operating goals. In order for the Company to meet future operating and debt service requirements, it will need to be successful in its growth, marketing and sales efforts. Additionally, where the Company experiences increased production and future sales, its current operational infrastructure may require changes to scale its business efficiently and effectively to keep pace with demand and achieve long-term profitability. If the Company's products and services are not accepted by new customers, the Company's operating results may be materially and adversely affected.

Achieving Publicly Announced Milestones

From time to time, the Company may announce the timing of certain events it expects to occur, such as the anticipated timing of results from clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval, or announcement of additional clinical trials for a prescription drug product candidate may ultimately vary from what is publicly disclosed. See "Commercial Scale Product Manufacturing", "Safety and Efficacy of Products", "Clinical Testing and Commercializing Product Candidates", "Completion of Clinical Trials", and "Nature of Regulatory Approvals" as discussed under this heading "Risk Factors" for further disclosure of risks and events that may affect the timing of certain events the Company may announce.

The Company undertakes no obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on the Company's business plan, financial condition or operating results and the trading price of the Common Shares.

Speculative Nature of Investment Risk

An investment in the securities of the Company carries a high degree of risk and should be considered as a speculative investment. The Company has no history of earnings, limited cash reserves, limited operating history, has not paid dividends, and is unlikely to pay dividends in the immediate or near future.

Early Stage of the Industry and Product Development

Given the early stage of its prescription drug product development, the Company can make no assurance that its research and development programs will result in regulatory approval or commercially viable products. To achieve profitable operations, the Company, alone or with others, must successfully develop, gain regulatory approval for, and market its future products. The Company currently has no products that have been approved by Health Canada, the FDA, the MHRA, the EMA, the PDD or any similar regulatory authority. To obtain regulatory approvals for its prescription drug product candidates being developed and to achieve commercial success, clinical trials must demonstrate that the prescription drug product candidates are safe for human use and that they demonstrate efficacy.

Many prescription drug product candidates never reach the stage of clinical testing and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Prescription drug product candidates can fail for a number of reasons, including, but not limited to, being unsafe for human use or due to the failure to provide therapeutic benefits equal to or better than the current standard of treatment at the time of testing. Unsatisfactory results obtained from a particular study relating to a research and development program may cause the Company or its collaborators to abandon commitments to that program. Positive results of early preclinical research may not be indicative of the results that will be obtained in later stages of preclinical or clinical research. Similarly, positive results from early-stage clinical trials may not be indicative of favorable outcomes in later-stage clinical trials, and the Company can make no assurance that any future studies, if undertaken, will yield favorable results.

The early stage of the Company's product development makes it particularly uncertain whether any of its product development efforts will prove to be successful and meet applicable regulatory requirements, and whether any of its prescription drug product candidates will receive the requisite regulatory approvals, be capable of being manufactured at a reasonable cost or be successfully marketed. If the Company is successful in developing its current and future prescription drug product candidates into approved products, it will still experience many potential obstacles, which would affect its ability to successfully market and commercialize such approved products, such as the need to develop or obtain manufacturing, marketing and distribution capabilities, price pressures from third-party payors, or proposed changes in health care systems. If the Company is unable to successfully market and commercialize any of its products, its financial condition and results of operations may be materially and adversely affected.

The Company can make no assurance that any future studies, if undertaken, will yield favorable results. Many companies in the pharmaceutical and biotechnology industries have suffered significant

setbacks in later-stage clinical trials after achieving positive results in early-stage development, and the Company cannot be certain that it will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events or latent defects in the manufactured drug product or the formulation or stability thereof. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their prescription drug product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain Health Canada, FDA or EMA approval. If the Company fails to produce positive results in future clinical trials and other programs, the development timeline and regulatory approval and commercialization prospects for the Company's leading prescription drug product candidates, and, correspondingly, its business and financial prospects, would be materially adversely affected.

Preclinical testing and clinical trials for the Company's products may not achieve the desired results. The results of preclinical testing and clinical trials are uncertain. Product approvals are subject to a number of contingencies and may not be obtained in the time expected or at all. The Company's products may not attract a following among patients, retailers and/or providers. The Company expects to face an inherent risk of exposure to product liability claims, regulatory action and litigation if the products it plans to distribute are alleged to have caused loss or injury. There can be no assurance that the Company will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities.

The Company's business relies on its ability to access, develop, and sell HLP003, HLP004, HLP005 and any other compounds the Company is developing or may develop. HLP003, HLP004, certain compounds being developed under the HLP005 Program, and other compounds being developed by the Company are controlled substances in many jurisdictions, including in Canada under Schedule III of the *Controlled Drugs and Substances Act* and in the United States. The Company may face difficulty accessing the public capital markets in Canada or the United States as a result of the response of regulators, stock exchanges, and other market participants to the Company's development and sale of a controlled substance. The Company may also have limited access to traditional banking services, as well as limited access to debt financing from traditional institutional lenders. The medical efficacy of HLP003, HLP004 and other compounds being developed under the HLP005 Program has not been confirmed and requires further study and scientific rigour.

Dependence on the HLP003 Program

The Company is currently prioritizing the advancement of its HLP003 Program, and a substantial majority of its resources are devoted to the PARADIGM Phase 3 program. The Company's near-term prospects and the market price of the Common Shares depend substantially on the success of HLP003, including the topline results of APPROACH expected in Q4 2026, the completion of EMBRACE and EXTEND, and the submission and acceptance of an NDA, regulatory approval and DEA rescheduling. If either APPROACH or EMBRACE does not meet its primary endpoint, or if HLP003 encounters safety, manufacturing, supply, labeling or regulatory issues, the Company may be required to delay, modify or discontinue the HLP003 Program, its ability to raise capital may be impaired, and its business, financial condition and prospects would be materially adversely affected.

Data May Be Negative or May Change

The Company reports data from its clinical trials from time to time. The Company's business and prospects, and the market price of the Common Shares, depend substantially on the results of its trial. If trials do not meet primary endpoints, or if the results are perceived as less favorable than expected, the Company may be required to modify, delay or discontinue its clinical trials, its ability to raise additional capital on acceptable terms or at all may be impaired, and the market price of the Common Shares could decline significantly. In particular, topline data are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline data. Regulatory authorities may not accept or agree with the Company's assumptions, estimates, calculations, conclusions or analyses, or may interpret or weigh the importance of the data differently, which could adversely affect the approvability of the Company's product candidates.

Regulatory Risks and Uncertainties

In Canada, certain drugs, including HLP003 and HLP004, are classified as Schedule III drugs under the CDSA and as such, medical and recreational use is illegal under Canadian federal laws. In the United States, certain serotonergic agonists, including HLP003 and HLP004, are classified as Schedule I drugs under the CSA and the Controlled Substances Import and Export Act and as such, medical and recreational use is illegal under the U.S. federal laws. Anyone wishing to conduct research on substances listed in Schedule I under the CSA must register with the DEA and obtain DEA approval of the research proposal. The EU member states currently classify HLP003 and HLP004 as a Schedule I substance under the UN 71 and, as such, a licence is required to produce, dispense, import or export any Schedule I substances, but the specific requirements vary from country to country. Currently in the Netherlands, HLP004 is classified as a List 1 Drug under the Dutch Opium Act and, as such, subject to express authorization being obtained, the production, trade and possession of HLP004 are prohibited. In the United Kingdom, HLP003 and HLP004 are controlled as a Class A drug under the MDA and Schedule 1 drug under the MDR. Schedule 1 drugs can only be lawfully manufactured, produced, possessed and supplied under a controlled drugs domestic licence issued by the UK Home Office.

There is no guarantee that HLP003, HLP004, compounds being developed under the HLP005 Program or any other compounds the Company may develop will ever be approved as medicines in any jurisdiction in which the Company operates. While the Company is focused on programs using serotonergic agonist compounds, the Company does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates and does not intend to have any such involvement. However, the laws and regulations generally applicable to the industry in which the Company is involved in may change in ways currently unforeseen. Any amendment to or replacement of existing laws or regulations, including the classification or re-classification of the substances the Company is developing or working with, which are matters beyond the Company's control, may cause the Company's business, financial condition, results of operations and prospects to be adversely affected or may cause the Company to incur significant costs in complying with such changes or it may be unable to comply therewith. A violation of any applicable laws and regulations of the jurisdictions in which the Company operates could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil

proceedings initiated by either government entities in the jurisdictions in which the Company operates, or private citizens or criminal charges.

The loss of the necessary licences and permits for any of the above scheduled drugs could have an adverse effect on the Company's operations.

The NSA segment of the drug industry is a fairly new industry and the Company cannot predict the impact of the ever-evolving compliance regime in respect of this industry. Similarly, the Company cannot predict the time required to secure all appropriate regulatory approvals for future products, or the extent of testing and documentation that may, from time to time, be required by governmental authorities. The impact of compliance regimes, any delays in obtaining, or failure to obtain regulatory approvals may significantly delay or impact the development of markets, its business and products, and sales initiatives and could have a material adverse effect on the business, financial condition and operating results of the Company.

The success of the Company's business is dependent on the reform of controlled substances laws pertaining to HLP003 and HLP004. If controlled substances laws are not favorably reformed in the United States, the UK, the EU, and other global jurisdictions, the commercial opportunity that the Company is pursuing may be highly limited.

The Company makes no medical, treatment or health benefit claims about the Company's proposed products. The FDA, Health Canada, the EMA or other similar regulatory authorities have not evaluated claims regarding HLP003, HLP004, or compounds being developed under the HLP005 Program. The efficacy of such products have not been confirmed by approved research. There is no assurance that the use of HLP003, HLP004, or compounds being developed under the HLP005 Program can diagnose, treat, cure or prevent any disease or condition. Vigorous scientific research and clinical trials are needed. The Company is currently conducting clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy and safety of potential products do not imply that the Company verified such in clinical trials or that the Company will complete such trials. If the Company cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on the Company's performance and operations.

Risks of Operating in Australia and European Countries

The Company is subject to additional risks related to operating in Australia and certain countries in Europe including: (i) differing regulatory requirements in Australia and Europe; (ii) unexpected changes in price and exchange controls and other regulatory requirements; (iii) increased difficulties in managing the logistics and transportation of collecting and shipping patient material; (iv) import and export requirements and restrictions; (v) compliance with tax, employment, immigration and labour laws for employees living or traveling abroad; (vi) foreign taxes, including withholding of payroll taxes; (vii) foreign currency fluctuations, which could result in increased operating expenses, and other obligations incident to doing business in another country; (viii) difficulties staffing and managing foreign operations; (ix) potential liability under the Corruption of Foreign Public Officials Act of Canada or comparable foreign regulations; (x) challenges enforcing its contractual and intellectual property rights, especially in Australia and those European countries that do not respect and protect intellectual property rights to the same extent as Canada or the United States; (xi)

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and (xii) business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with the Company's international operations may materially adversely affect its ability to attain or maintain profitable operations.

"Foreign Private Issuer" Status Under U.S. Securities Laws

The Company is a "foreign private issuer", under applicable U.S. federal securities laws, and is, therefore, not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, the Company is subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. As a result, the Company does not file the same reports that a U.S. domestic issuer would file with the SEC, although the Company is required to file with or furnish to the United States Securities and Exchange Commission (the "**SEC**") the continuous disclosure documents that it is required to file in Canada under Canadian securities laws. In addition, the Company's officers, directors, and principal shareholders are exempt from the reporting and short-swing profit recovery provisions of Section 16 of the Exchange Act. Therefore, the Company's shareholders may not know on as timely a basis when the Company's officers, directors and principal shareholders purchase or sell Common Shares, as the reporting periods under the corresponding Canadian insider reporting requirements are longer.

As a foreign private issuer, the Company is exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements. The Company is also exempt from Regulation FD, which prohibits issuers from making selective disclosures of material non-public information. While the Company complies with the corresponding requirements relating to proxy statements and disclosure of material non-public information under Canadian securities laws, these requirements differ from those under the Exchange Act and Regulation FD and shareholders should not expect to receive the same information at the same time as such information is provided by U.S. domestic companies. In addition, the Company may not be required under the Exchange Act to file annual and quarterly reports with the SEC as promptly as U.S. domestic companies whose securities are registered under the Exchange Act. Accordingly, there may be less publicly available information concerning the Company than there would be if it were not a foreign private issuer.

Home Country Corporate Governance Practices

As a foreign private issuer listed on Nasdaq, the Company is permitted to follow Canadian corporate law and the OBCA with respect to certain aspects of corporate governance in lieu of certain requirements under Nasdaq listing standards. Some corporate governance practices under Canadian law and the OBCA may differ from Nasdaq corporate governance listing standards.

For example, the Company is exempt from Nasdaq regulations that require a listed U.S. company to:

- Follow a minimum quorum requirement for a meeting of shareholders of 33 1/3% of the outstanding Common Shares; and

- Seek shareholder approval for certain types of securities issuances at the thresholds required under Nasdaq listing standards.

Currently, the Company generally follows home country practice and takes advantage of the above exceptions. The Company remains subject to the corporate governance requirements of the OBCA, applicable Canadian securities laws, including National Instrument 52-110 – *Audit Committees* and National Instrument 58-101 – *Disclosure of Corporate Governance Practices*, and the rules of Cboe Canada. However, such requirements differ from Nasdaq corporate governance listing standards and, therefore, the Company's shareholders may not be afforded the same protection under corporate governance listing standards applicable to U.S. domestic issuers.

The Company May Lose "Foreign Private Issuer" Status in the Future

In order to maintain the Company's current status as a "foreign private issuer", a majority of the Common Shares must be either directly or indirectly held of record by non-residents of the United States unless the Company also satisfies one of the additional requirements necessary to preserve this status. The Company would in the future lose its foreign private issuer status if a majority of the Common Shares are held of record by United States residents and the Company fails to meet the additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to the Company under U.S. federal securities laws as a U.S. domestic issuer may be significantly more than the costs it incurs as a Canadian foreign private issuer eligible to use the Multijurisdictional Disclosure System established between Canada and the United States (the "**MJDS**"). If the Company is not a foreign private issuer, it would not be eligible to use the MJDS or other foreign issuer forms and would be required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. Additionally, the Company would lose the ability to rely upon exemptions from Nasdaq corporate governance requirements that are available to foreign private issuers such as the ones described above.

Plans for Growth

The Company intends to continue to advance its research and development programs and operations over the next 12 to 24 months. This advancement will place a significant strain on the Company's management systems and resources. The Company may not be able to implement its business strategy in a rapidly evolving market. In particular, the Company may be required to manage multiple relationships with various strategic industry participants and other third parties, which relationships could be strained. Similarly, an increase in the number of third-party relationships the Company has, may lead to management of the Company being unable to manage growth effectively. The occurrence of such events may result in the Company being unable to successfully identify, manage and exploit existing and potential market opportunities.

Limited Products

The Company will be heavily reliant on the production and distribution of NSAs and related products. If they do not achieve sufficient market acceptance, it will be difficult for the Company to achieve profitability.

The Company's revenue will be derived almost exclusively from sales of NSA pharmaceutical products, and the Company expects that its NSA pharmaceutical products will account for substantially all of its revenue for the foreseeable future. If the NSA pharmaceutical market segment declines or fails to achieve substantially greater market acceptance than it currently enjoys, the Company will not be able to grow its revenues sufficiently for it to achieve consistent profitability.

Even if products to be distributed by the Company conform to international safety and quality standards, sales could be adversely affected if consumers in target markets lose confidence in the safety, efficacy, and quality of NSA pharmaceutical products. Adverse publicity about serotonergic agonist pharmaceutical products, similar to those that the Company may sell or the NSAs that the Company may sell could discourage consumers from buying products distributed by the Company.

Limited Marketing and Sales Capabilities

The Company will, for the immediate future, have limited marketing and sales capabilities, and there can be no assurance that it will be able to develop or acquire these capabilities at the level needed to produce and deliver for sale, through industry partners, its products in sufficient commercial quantities. Further, there can be no assurance that the Company, either on its own or through arrangements with other industry participants, will be able to develop or acquire such capabilities on a cost-effective basis, or at all. Finally, there can be no assurance that the Company's industry partners will be able to market or sell the Company's products in compliance with requisite regulatory protocols or on a cost-effective basis. The Company's dependence upon third parties for the production, and marketing or sale, as applicable, of the Company's products could have a material adverse effect on the Company's business, financial condition and results of operations.

No Assurance of Commercial Success

The successful commercialization of the Company's products will depend on many factors, including, the Company's ability to establish and maintain working partnerships with industry participants in order to market its products, the Company's ability to supply a sufficient amount of its products to meet market demand, and the number of competitors within each jurisdiction within which the Company may from time to time be engaged. There can be no assurance that the Company or its industry partners will be successful in their respective efforts to develop and implement, or assist the Company in developing and implementing, a commercialization strategy for the Company's products.

No Profits or Significant Revenues

The Company has no history upon which to evaluate its performance and future prospects. The Company's proposed operations are subject to all the business risks associated with new enterprises. These include likely fluctuations in operating results as the Company makes significant investments in research, development and product opportunities, and reacts to developments in its market, including purchasing patterns of customers, and the entry of competitors into the market. The Company will only be able to pay dividends on any shares once its directors determine that it is financially able to do

so. The Company cannot make any assurance that it will be profitable in the next three years or generate sufficient revenues to pay dividends to the holders of the Common Shares.

Reliance on Third Parties for Clinical Development Activities

The Company relies and will continue to rely on third parties to conduct a significant portion of its preclinical and clinical development activities. For example, clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in its relationship with third parties, or if it is unable to provide quality services in a timely manner and at a feasible cost, the Company's active development programs will face delays. Further, if any of these third parties fails to perform as the Company expects or if their work fails to meet regulatory requirements, the Company's testing could be delayed, cancelled or rendered ineffective. These third parties may experience staffing shortages and attrition, become financially distressed, change their priorities, form relationships with the Company's competitors or become subject to trade restrictions or sanctions. The Company's reliance on these third parties does not relieve it of its regulatory responsibilities, and if the quality or accuracy of clinical data is compromised, the Company may be required to repeat or extend its clinical trials. If any of these relationships terminates, the Company may not be able to enter into arrangements with alternative providers in a timely manner or on acceptable terms.

Risks Related to Third Party Relationships

The Company intends to enter into strategic alliances with third parties that the Company believes will complement or augment its proposed business or will have a beneficial impact on the Company. Strategic alliances could present unforeseen integration obstacles or costs, may not enhance the Company's business, and may involve risks that could adversely affect the Company, including significant amounts of management time that may be diverted from operations in order to pursue and complete such transactions or maintain such strategic alliances. Future strategic alliances could result in the incurrence of additional debt, costs and contingent liabilities, and there can be no assurance that future strategic alliances will achieve, or that the Company's existing strategic alliances will continue to achieve, the expected benefits to the Company's business or that the Company will be able to consummate future strategic alliances on satisfactory terms, or at all. Any of the foregoing could have a material adverse effect on the Company's business, financial condition and results of operations.

In addition to the foregoing, the success of the Company's business will depend, in large part, on the Company's ability to enter into, and maintain collaborative arrangements with various participants in the pharmaceutical industry. There can be no assurance that the Company will be able to enter into collaborative arrangements in the future on acceptable terms, if at all. There can be no assurance that such arrangements will be successful, that the parties with which the Company has or may establish arrangements will adequately or successfully perform their obligations under such arrangements, that potential partners will not compete with the Company by seeking or prioritizing alternate, competitor products. The termination or cancellation of any such collaborative arrangement or the failure of the Company and/or the other parties to these arrangements to fulfill their obligations could have a material adverse effect on the Company's business, financial condition and results of operations. In

addition, disagreements between the Company and any of its industry partners could lead to delays or time consuming and expensive legal proceedings, which could have a material adverse effect on the Company's business, financial condition and results of operations.

Reliance on Contract Manufacturers

The Company has limited manufacturing experience and relies on contract manufacturing organizations ("**CMOs**") to manufacture its prescription drug product candidates for preclinical studies and clinical trials. The Company relies on CMOs for manufacturing, filling, packaging, storing and shipping of drug product in compliance with cGMP regulations applicable to its products. All applicable jurisdictions, including Health Canada, the FDA,the MHRA the EMA, and the PDD, ensure the quality of food, drug products and dietary supplements by carefully monitoring drug manufacturers' compliance with cGMP regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product. There can be no assurances that CMOs will be able to meet the Company's timetable and requirements. The Company has not contracted with alternate suppliers for drug substance production in the event that the current provider is unable to scale up production, or if it otherwise experiences any other significant problems. If the Company is unable to arrange for alternative third-party manufacturing sources on commercially reasonable terms or in a timely manner, the Company may be delayed in the development of its prescription drug product candidates. Further, CMOs must operate in compliance with cGMP and ensure that their appropriate permits and licences remain in good standing and failure to do so could result in, among other things, the disruption of product supplies. The Company's dependence upon third parties for the manufacture of its products may adversely affect its profit margins and its ability to develop and deliver products on a timely and competitive basis.

Because HLP003 and HLP004 are controlled substances, the Company's manufacturers, suppliers, importers and clinical sites must obtain and maintain controlled-substance registrations, licences and permits in each relevant jurisdiction, including DEA registrations and, for Schedule I substances manufactured in the United States, DEA manufacturing and procurement quotas, as well as import and export permits for each shipment of API to clinical sites outside the United States. The Company currently relies on a single provider for HLP003 API. Any delay or refusal by a regulatory authority to grant or renew such registrations, quotas or permits, or any loss of or disruption at that provider, could delay or interrupt supply to the Company's clinical trials, including PARADIGM, and could materially adversely affect the Company's business.

Safety and Efficacy of Products

Before obtaining marketing approval from regulatory authorities for the sale of the Company's prescription drug product candidates, the Company must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the prescription drug product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or

unacceptable safety profiles, notwithstanding promising results in earlier trials. The Company does not know whether the clinical trials it may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of its prescription drug product candidates in any jurisdiction. A prescription drug product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk the Company faces is the possibility that none of its prescription drug product candidates under development will successfully gain market approval from Health Canada, the FDA, the MHRA, the EMA, the PDD or other regulatory authorities, resulting in the Company being unable to derive any commercial revenue from them after investing significant amounts of capital in their development.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any such product can be achieved. As with the results of any statistical sampling, the Company cannot be sure that all side effects of its products may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to such product for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects, or the duration of such studies may not be sufficient to identify when those events may occur. There have been products that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of such products from the market, and the Company's products may be subject to similar risks. The Company might have to withdraw or recall its products from the marketplace. The Company may also experience a significant drop in the potential future sales of its products if and when regulatory approvals for such products are obtained, experience harm to its reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of the Company's products, or substantially increase the costs and expenses of commercializing and marketing its products.

Clinical Testing and Commercializing Products

Before obtaining marketing approval from regulatory authorities for the sale of the Company's prescription drug product candidates, it must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the prescription drug product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. The Company does not know whether the clinical trials it may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of its prescription drug product candidates in any jurisdiction. A prescription drug product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk the Company faces is the possibility that none of its prescription drug product candidates under development will successfully gain market approval from the FDA, or other regulatory

authorities, resulting in the Company being unable to derive any commercial revenue from this business segment after investing significant amounts of capital in its development.

The Company cannot predict whether any clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. The Company's product development costs will increase if it experiences delays in clinical testing. Significant clinical trial delays could shorten any periods during which the Company may have the exclusive right to commercialize its prescription drug product candidates or allow its competitors to bring products to market before the Company, which would impair the Company's ability to successfully commercialize its prescription drug product candidates and may harm its financial condition, results of operations and prospects.

The commencement and completion of clinical trials for the Company's prescription drug product candidates may be delayed for a number of reasons, including but not limited, to:

- failure by regulatory authorities to grant permission to proceed or placing clinical trials on hold;
- suspension or termination of clinical trials by regulators for many reasons, including concerns about patient safety or failure of the Company's CMOs to comply with cGMP requirements or latent defects in product quality;
- any changes to the Company's manufacturing process that may be necessary or desired, delays or failure to obtain clinical supply from CMOs of the Company's products necessary to conduct clinical trials;
- prescription drug product candidates demonstrating a lack of safety or efficacy during clinical trials, reports of clinical testing on similar technologies and products raising safety or efficacy concerns;
- clinical investigators not performing the Company's clinical trials on their anticipated schedule, dropping out of a trial, or employing methods not consistent with the clinical trial protocol, regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner;
- failure of the Company's contract research organizations to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical trial sites by regulatory authorities;
- methodological challenges associated with clinical trials of psychoactive compounds, including functional unblinding, expectancy effects, the design of an appropriate comparator arm and protocols for participant monitoring during dosing sessions, which could hinder the interpretability or regulatory acceptability of the Company's clinical trial results;
- regulatory authorities or ethics committees finding regulatory violations that require the Company to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- one or more regulatory authorities or ethics committees rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- failure to reach agreement on acceptable terms with prospective clinical trial sites.

The Company's product development costs will increase if it experiences delays in testing or approval or if the Company needs to perform more or larger clinical trials than planned. Additionally, changes

in regulatory requirements and policies may occur, and the Company may need to amend study protocols to reflect these changes. Amendments may require the Company to resubmit its study protocols to regulatory authorities or ethics committees for re-examination, which may impact the cost, timing or successful completion of that trial. Delays or increased product development costs may have a material adverse effect on the Company's business, financial condition and prospects.

Prior to commencing clinical trials in Canada, the United States, the UK, the Netherlands, or other jurisdictions, for any prescription drug product candidates developed by the Company, it may be required to have an IND (or equivalent) for each prescription drug product candidate and to file additional INDs prior to initiating any additional clinical trials. The Company believes that the data from its studies will support the filing of additional INDs to enable the Company to undertake additional clinical studies as it has planned. However, submission of an IND (or equivalent) may not result in the FDA (or equivalent authorities) allowing further clinical trials to begin and, once begun, issues may arise that will require the Company to suspend or terminate such clinical trials.

Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, these regulatory authorities may change their requirements in the future. Failure to submit or have effective INDs (or equivalent) and commence or continue clinical programs will significantly limit its opportunity to generate revenue.

Completion of Clinical Trials

As the Company's prescription drug product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, the Company will need to enroll an increasing number of patients that meet its eligibility criteria. There is significant competition for recruiting patients in clinical trials, and the Company may be unable to enroll the patients it needs to complete clinical trials on a timely basis or at all. The factors that affect the Company's ability to enroll patients are largely uncontrollable and include, but are not limited to, the size and nature of the patient population, eligibility and exclusion criteria for the trial, design of the clinical trial, competition with other companies for clinical sites or patients, perceived risks and benefits of the prescription drug product candidate, and the number, availability, location and accessibility of clinical trial sites.

Commercial Grade Product Manufacturing

The Company's prescription drug products will be manufactured in small quantities for preclinical studies and clinical trials by third party manufacturers. In order to commercialize its product, the Company needs to manufacture commercial quality drug supply for use in registration clinical trials. Most, if not all, of the clinical material used in Phase 3/pivotal/registration studies must be derived from the defined commercial process including scale, manufacturing site, process controls and batch size. If the Company has not scaled up and validated the commercial production of its product prior to the commencement of pivotal clinical trials, it may have to employ a bridging strategy during the trial to demonstrate equivalency of early-stage material to commercial drug product, or potentially delay the initiation or completion of the trial until drug supply is available. The manufacturing of commercial quality product may have long lead times, may be very expensive and requires significant

efforts including, but not limited to, scale-up of production to anticipated commercial scale, process characterization and validation, analytical method validation, identification of critical process parameters and product quality attributes, and multiple process performance and validation runs. If the Company does not have commercial drug supply available when needed for pivotal clinical trials, the Company's regulatory and commercial progress may be delayed, and it may incur increased product development costs. This may have a material adverse effect on the Company's business, financial condition and prospects, and may delay marketing of the product.

Nature of Regulatory Approvals

The Company's development and commercialization activities and prescription drug product candidates are significantly regulated by a number of governmental entities, including Health Canada, the FDA, the MHRA, the EMA and the PDD. Regulatory approvals are required prior to each clinical trial and the Company may fail to obtain the necessary approvals to commence or continue clinical testing. The Company must comply with regulations concerning the manufacture, testing, safety, effectiveness, labeling, documentation, advertising, and sale of products and prescription drug product candidates and ultimately must obtain regulatory approval before it can commercialize a prescription drug product candidate. The time required to obtain approval by such regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials. Any analysis of data from clinical activities the Company performs is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Even if the Company believes results from its sponsored clinical trials are favorable to support the marketing of its prescription drug product candidates, Health Canada, the FDA, the MHRA, the EMA the PDD or other regulatory authorities may disagree. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a prescription drug product candidate's clinical development and may vary among jurisdictions.

The Company has not obtained regulatory approval for any prescription drug product candidate and it is possible that none of its existing prescription drug product candidates or any future prescription drug product candidates will ever obtain regulatory approval. The Company could fail to receive regulatory approval for its prescription drug product candidates for many reasons, including, but not limited to failure to demonstrate that a prescription drug product candidate is safe and effective for its proposed indication, failure of clinical trials to meet the level of statistical significance required for approval, failure to demonstrate that a prescription drug product candidate's clinical and other benefits outweigh its safety risks, or deficiencies in the manufacturing processes or the failure of facilities of CMOs with whom the Company contracts for clinical and commercial supplies to pass a pre-approval inspection.

A regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and the Company's commercialization plans, or the Company may decide to abandon the development program. If the Company were to obtain approval, regulatory authorities may approve any of its prescription drug product candidates for fewer or more limited indications than the Company request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a prescription drug product

candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that prescription drug product candidate. Moreover, depending on any safety issues associated with the Company's prescription drug product candidates that garner approval, Health Canada, the FDA, the MHRA, the EMA, the PDD or other regulatory authorities may impose a risk evaluation and mitigation strategy, thereby imposing certain restrictions on the sale and marketability of such products.

If there are changes in the application of legislation, regulations or regulatory policies, or if problems are discovered with the Company products, or if one of its distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on the Company, imposing restrictions on the Company's products or its manufacture and requiring the Company to recall or remove its products from the market. The regulators could also suspend or withdraw the Company's co-marketing authorizations, requiring it to conduct additional clinical trials, change its labeling or submit additional applications for marketing authorization. If any of these events occurs, the Company's ability to sell its products may be impaired, and it may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect its business, financial condition and results of operations.

Market Access and Acceptance

The Company may never have a product that is commercially successful. To date, the Company has no product authorized for marketing. The Company's future products require further clinical investigation, regulatory review, significant market access and marketing efforts and substantial investment before it can produce any revenue. Furthermore, if approved, the Company's product may not achieve an adequate level of acceptance by payors, health technology assessment bodies, healthcare professionals, patients and the medical community at large, and the Company may not become profitable. The level of acceptance the Company ultimately achieves may be affected by negative public perceptions and historic media coverage of serotonergic agonist substances, including those resulting in non-ordinary states of consciousness. Because of this history, efforts to educate the medical community and third-party payors and health technologies assessment bodies on the benefits of company's product compounds may require significant resources and may never be successful, which would prevent the Company from generating significant revenue or becoming profitable. Market acceptance of the Company's future products by healthcare professionals, patients, healthcare payors and health technology assessment bodies will depend on a number of factors, many of which are beyond the Company's control, including, but not limited to, the following:

- acceptance by healthcare professionals, patients and healthcare payors of each product as safe, effective and cost-effective;
- changes in the standard of care for the targeted indications for any product;
- the strength of sales, marketing and distribution support;
- potential product liability claims;
- the product's relative convenience, ease of use, ease of administration and other perceived advantages over alternatives;
- the prevalence and severity of adverse events or publicity;

- limitations, precautions or warnings listed in the summary of product characteristics, patient information leaflet, package labeling or instructions for use;
- the cost of treatment with the Company's product in relation to alternatives;
- the steps that prescribers and dispensers must take, as well as the perceived risks based upon its controlled substance status;
- the ability to manufacture the Company's product in sufficient quantities and yields with adequate purity;
- the availability and amount of coverage and reimbursement from healthcare payors, and the willingness of patients to pay out of pocket in the absence of healthcare payor coverage or adequate reimbursement;
- the willingness of the target patient population to try, and of healthcare professionals to prescribe, the product;
- any potential unfavorable publicity, including negative publicity associated with recreational use or abuse of non-deuterated forms of the Company's NSAs or other serotonergic agonist compounds; and
- any restrictions on the use, sale or distribution of the Company's future products.

If the Company's future products fail to gain market access and acceptance, this will have a material adverse impact on the Company's ability to generate revenue to provide a satisfactory, or any, return on the Company's investments. Even if some products achieve market access and acceptance, the market may prove not to be large enough to allow the Company to generate significant revenue.

The Company must rely largely on its own market research to forecast sales as detailed forecasts are not generally obtainable from other sources at this early stage of the industry segment. A failure in the demand for the Company's products to materialize as a result of competition, technological change or other factors could have a material adverse effect on the business, results of operations and financial condition of the Company.

Unfavorable Publicity or Consumer Perception

The Company believes that the serotonergic agonist pharmaceutical industry segment is highly dependent upon consumer perception regarding the safety, efficacy and quality of the pharmaceutical products. Consumer perception of the Company's pharmaceutical products can be significantly influenced by scientific research or findings, regulatory investigations, litigation, media attention and other publicity regarding the consumption of serotonergic agonists. There can be no assurance that future scientific research, findings, regulatory proceedings, litigation, media attention or other research findings or publicity will be favorable to the serotonergic agonist pharmaceutical industry segment or any particular product, or consistent with earlier publicity. Future research reports, findings, regulatory proceedings, litigation, media attention or other publicity that are perceived as less favorable than, or that question, earlier research reports, findings or publicity could have a material adverse effect on the demand for the Company's NSA products and the business, results of operations, financial condition and cash flows of the Company. The Company's dependence upon consumer perceptions means that adverse scientific research reports, findings, regulatory proceedings, litigation, media attention or other publicity, whether or not accurate or with merit, could have a material adverse effect on the Company, the demand for the Company's NSA products, and the

business, results of operations, financial condition and cash flows of the Company. Further, adverse publicity reports or other media attention regarding the safety, efficacy and quality of serotonergic agonist products in general, or the Company's NSA products and services specifically or associating the consumption of serotonergic agonists with illness or other negative effects or events, could have such a material adverse effect. Such adverse publicity reports or other media attention could arise even if the adverse effects associated with such products resulted from consumers' failure to consume such products legally, appropriately or as directed.

The serotonergic agonist pharmaceutical industry segment is highly dependent upon consumer perception regarding the medical benefits, safety, efficacy and quality of the medicine distributed for medical purposes to such consumers. There can be no assurance that future scientific research or findings on the medical benefits, viability, safety, efficacy and dosing of HLP003, HLP004, or compounds being developed under the HLP005 Program, regulatory proceedings, litigation, media attention or other research findings or publicity will be favorable to the industry or the Company or any particular product, or consistent with earlier publicity.

Social Media

There has been a marked increase in the use of social media platforms and similar channels that provide individuals with access to a broad audience of consumers and other interested persons. The availability and impact of information on social media platforms is virtually immediate and many social media platforms publish user-generated content without filters or independent verification as to the accuracy of the content posted. Information posted about the Company may be adverse to the Company's interests or may be inaccurate, each of which may harm the Company's business, financial condition and results of operations.

Biotechnology and Pharmaceutical Market Competition

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. The Company's competitors include large, well-established pharmaceutical companies, biotechnology companies, and academic and research institutions developing therapeutics for the same indications the Company is targeting and competitors with existing marketed therapies. Many other companies are developing or commercializing therapies to treat the same diseases or indications for which the Company's prescription drug product candidates may be useful. Some competitors use therapeutic approaches that may compete directly with the Company's prescription drug product candidates.

Many of the Company's competitors have substantially greater financial, technical and human resources than the Company does and have significantly greater experience than the Company in conducting preclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of products. Accordingly, the Company's competitors may succeed in obtaining regulatory approval for products more rapidly than the Company does. The Company's ability to compete successfully will largely depend on:

- the efficacy and safety profile of its prescription drug product candidates relative to marketed products and other prescription drug product candidates in development;
- the Company's ability to develop and maintain a competitive position in the product categories and technologies on which it focuses;
- the time it takes for the Company's prescription drug product candidates to complete clinical development and receive marketing approval;
- the Company's ability to obtain required regulatory approvals;
- the Company's ability to commercialize any of its prescription drug product candidates that receive regulatory approval;
- the Company's ability to establish, maintain and protect intellectual property rights related to its prescription drug product candidates; and
- acceptance of any of the Company's prescription drug product candidates that receive regulatory approval by physicians and other healthcare providers and payers.

Competitors have developed and may develop technologies that could be the basis for products that challenge the discovery research capabilities of prescription drug product candidates the Company is developing. Some of those products may have an entirely different approach or means of accomplishing the same desired therapeutic effect than the Company's prescription drug product candidates and may be more effective or less costly than its prescription drug product candidates. The success of the Company's competitors and their products and technologies relative to the Company's technological capabilities and competitiveness could have a material adverse effect on the future preclinical studies and clinical trials of the Company's prescription drug product candidates, including its ability to obtain the necessary regulatory approvals for the conduct of such clinical trials. This may further negatively impact the Company's ability to generate future product development programs using serotonergic agonist based compounds.

If the Company is not able to compete effectively against its current and future competitors, the Company's business will not grow, and its financial condition and operations will substantially suffer.

Further, there can be no assurance that potential competitors of the Company, which may have greater financial, cultivation, production, sales and marketing experience, and personnel and resources than the Company, are not currently developing, or will not in the future develop, products and strategies that are equally or more effective and/or economical as any products or strategies developed by the Company or which would otherwise render the Company's business, products and strategies, as applicable, ineffective, or obsolete. Increased competition by larger and better financed competitors could materially and adversely affect the business, financial condition and results of operations of the Company.

Reliance on Key Executives and Scientists

The loss of key members of the Company's staff, could harm the Company. For example, the Company has experienced significant changes in its senior management during 2026, including changes in the role of Chief Executive Officer and the departure of its co-founders from their executive and consulting roles. Management transitions subject the Company to risks, including the failure to transition responsibilities and tasks effectively, the loss of historical knowledge and relationships, disruption to its corporate culture and the diversion of management attention. The

Company has employment agreements with all key members of its staff, although such employment agreements do not guarantee their retention. The Company also depends on its scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability to the Company. In addition, the Company believes that its future success will depend in large part upon its ability to attract and retain highly skilled scientific, managerial, medical, manufacturing, clinical and regulatory personnel, particularly as the Company expands its activities and seeks regulatory approvals for clinical trials. The Company enters into agreements with its scientific and clinical collaborators and advisors, key opinion leaders and academic partners in the ordinary course of its business. Should key academic and scientific personnel including employees or collaborative partners who work on the development of the Company's research activities leave, the Company's current and future development programs may be delayed or adversely affected. Notwithstanding these arrangements, the Company faces significant competition for these types of personnel from other companies, research and academic institutions, government entities and other organizations. The Company cannot predict its success in hiring or retaining the personnel it requires for continued growth. In addition, due to limited financial resources, the Company may not be able to successfully expand its operations due to challenges in recruiting and training qualified new staff. Expansion of personnel may result in significant diversion of management time and resources. The loss of the services of any of the Company's executive officers or other key personnel could potentially harm its business, operating results or financial condition.

Employee Misconduct

Notwithstanding having established a code of ethics and business conduct (see the AIF for further details), the Company is exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with Health Canada, the FDA the MHRA the EMA the PDD, and other comparable international authorities' regulations, provide accurate information to Health Canada, the FDA the MHRA, the EMA, and/or the PDD, comply with manufacturing standards the Company has established, comply with federal and provincial healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to the Company. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to the Company's reputation. If any such actions are instituted against the Company, and the Company is not successful in defending itself or asserting its rights, those actions could have a substantial impact on the Company's business and results of operations, including the imposition of substantial fines or other sanctions.

Business Expansion and Growth

The Company may in the future seek to expand its pipeline and capabilities by acquiring one or more companies or businesses, entering into collaborations, or in-licensing one or more prescription drug product candidates. Acquisitions, collaborations and in-licences involve numerous risks, including,

but not limited to substantial cash expenditures, technology development risks, potentially dilutive issuances of equity securities, incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition, difficulties in assimilating the operations of the acquired companies, entering markets in which the Company has limited or no direct experience, and potential loss of the Company's key employees or key employees of the acquired companies or businesses.

The Company cannot provide assurance that any acquisition, collaboration or in-licence will result in short-term or long-term benefits to it. The Company may incorrectly judge the value or worth of an acquired company or business or in-licensed prescription drug product candidate. In addition, the Company's future success would depend in part on its ability to manage the rapid growth associated with some of these acquisitions, collaborations and in-licences. The Company cannot provide assurance that it would be able to successfully combine its business with that of acquired businesses, manage a collaboration or integrate in-licensed prescription drug product candidates. Furthermore, the development or expansion of the Company's business may require a substantial capital investment by the Company.

Negative Results of External Clinical Trials or Studies

From time to time, studies or clinical trials on various aspects of breakthrough neuropsychiatry products are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the breakthrough neuropsychiatry product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to the Company's prescription drug product candidates, or the therapeutic areas in which the Company's prescription drug product candidates compete, could adversely affect its share price and the Company's ability to finance future development of its prescription drug product candidates, and its business and financial results could be materially and adversely affected.

Product Liability

The Company currently does not carry any product liability insurance coverage. Even though the Company is not aware of any product liability claims at this time, its business exposes itself to potential product liability, recalls and other liability risks that are inherent in the testing of product candidates and, if approved, the commercialization and sale of consumer products. The Company can provide no assurance that such potential claims will not be asserted against it. A successful liability claim or series of claims brought against the Company could have a material adverse effect on its business, financial condition and results of operations.

Although the Company intends to obtain adequate product liability insurance, it cannot provide any assurances that it will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability cover that may be obtained by the Company could have a material adverse effect on its business, financial condition and results of operations.

Some of the Company's agreements with third parties might require it to maintain product liability insurance. If the Company cannot obtain acceptable amounts of coverage on commercially reasonable terms in accordance with the terms set forth in these agreements, the corresponding agreements would be subject to termination, which could have a material adverse impact on its operations.

Enforcing Contracts

Due to the nature of the business of the Company and the fact that certain of its contracts involve HLP003 and HLP004, the use of which is not legal under Canadian or U.S. federal law and in certain other jurisdictions, the Company may face difficulties in enforcing its contracts in Canadian or U.S. federal and state courts. The inability to enforce any of its contracts could have a material adverse effect on its business, operating results, financial condition or prospects.

In order to manage its contracts with contractors, the Company will ensure that such contractors are appropriately licensed. Were such contractors to operate outside the terms of these licences, the Company may experience an adverse effect on its business, including the pace of development of its product.

Product and Material Recalls

Manufacturers, producers and distributors of products are sometimes subject to the recall or return of their products for a variety of reasons, including product defects, such as contamination, unintended harmful side effects or interactions with other substances, packaging safety storage deficiencies and inadequate or inaccurate labelling disclosure. If any of the Company's products are recalled due to an alleged product defect or for any other reason, the Company could be required to incur the unexpected expense of the recall and any legal proceedings that might arise in connection with the recall. The Company may have to recall material being used in a clinical trial resulting in delays to the trial and additional manufacturing expenses, if further drug product is required. If the product is already commercialized, the Company may lose a significant amount of sales and may not be able to replace those sales at an acceptable margin or at all. In addition, a product recall may require significant management attention.

Although the Company's suppliers have detailed procedures in place for testing its products, there can be no assurance that any quality, potency or contamination problems will be detected in time to avoid unforeseen product recalls, regulatory action or lawsuits. Additionally, if the Company is subject to recall, the image of the Company could be harmed. A recall for any of the foregoing reasons could lead to decreased demand for the Company's products and could have a material adverse effect on the results of operations and financial condition of the Company. Additionally, product recalls may lead to increased scrutiny of the Company's operations by regulatory agencies, requiring further management attention, potential loss of applicable licences and potential legal fees and other expenses.

Distribution and Supply Chain Interruption

The Company is susceptible to risks relating to distributor and supply chain interruptions. Distribution in the U.S., Canada, the EU, the UK and other jurisdictions will be largely accomplished through independent contractors, therefore, an interruption (e.g., a labour strike) for any length of time affecting such independent contractors may have a significant impact on the Company's ability to sell or manufacture its products. Supply chain interruptions, including a production or inventory disruption, could impact product quality and availability. Inherent to producing products is a potential for shortages or surpluses in future years if demand and supply are materially different from long-term forecasts.

Difficulty to Forecast

The Company must rely largely on its own market research to forecast sales as detailed forecasts are not generally obtainable from other sources at this early stage of the serotonergic agonist pharmaceutical industry segment. A failure in the demand for the Company's NSA pharmaceutical industry products to materialize as a result of competition, technological change or other factors could have a material adverse effect on the business, results of operations and financial condition of the Company.

Promoting the Brand

Promoting the Company's brand will be critical to creating and expanding a customer base. Promoting the brand will depend largely on the Company's ability to provide NSA pharmaceutical products to the market. Further, the Company may, in the future, introduce new products or services that its customers do not like, which may negatively affect the brand and reputation. If the Company fails to successfully promote its brand or if it incurs excessive expenses in this effort, its business and financial results from operations could be materially adversely affected.

If there are changes in the applicable regulatory framework governing the promotion, branding and marketing of the Company's products, the Company's ability to promote and sell its products may be impaired, and it may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect its business, financial condition and results of operations.

Product Viability

If the Company's pharmaceutical products are not perceived to have the effects intended by the end user, the Company's business may suffer. In general, pharmaceutical products in the class of drugs including HLP003 and HLP004 have minimal long-term data with respect to efficacy, unknown side effects and/or interaction with individual human biochemistry or other supplements or medications. As a result, the Company's pharmaceutical products could have certain side effects if not used as directed or if taken by an end user that has certain known or unknown medical conditions.

Success of Quality Control Systems

The quality and safety of the Company's products are critical to the success of its business and operations. As such, it is imperative that the Company (and its service providers') quality control systems operate effectively and successfully. Quality control systems can be negatively impacted by the design of the quality control systems, the quality of training programs and adherence by employees to quality control guidelines. Any significant failure or deterioration of such quality control systems could have a material adverse effect on the Company's business and operating results.

Reliance on Key Inputs

The Company's business is expected to be dependent on a number of key inputs and their related costs including raw materials and supplies. Any significant interruption or negative change in the availability or economics of the supply chain for key inputs could materially impact the business, financial condition and operating results of the Company. Any inability to secure required supplies and services or to do so on appropriate terms could have a materially adverse impact on the business, financial condition and operating results of the Company.

Liability Arising from Fraudulent or Illegal Activity

The Company is exposed to the risk that its employees, independent contractors, consultants, service providers and licensors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional undertakings of unauthorized activities, or reckless or negligent undertakings of authorized activities, in each case on the Company's behalf or in its service that violate (i) various laws and regulations, including healthcare laws and regulations, (ii) laws that require the true, complete and accurate reporting of financial information or data, (iii) the terms of the Company's agreements with third parties. Such misconduct could expose the Company to, among other things, class actions and other litigation, increased regulatory inspections and related sanctions, and lost sales and revenue or reputational damage.

The precautions taken by the Company to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting the Company from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Such misconduct may result in legal action, significant fines or other sanctions and could result in loss of any regulatory licence held by the Company at such time. The Company may be subject to security breaches at its facilities or in respect of electronic document or data storage, which could lead to breaches of applicable privacy laws and associated sanctions or civil or criminal penalties; events, including those beyond the control of the Company, may damage its operations. In addition, these events may negatively affect customers' demand for the Company's products. Such events include, but are not limited to, non-performance by third party contractors; increases in materials or labour costs; breakdown or failure of equipment; failure of quality control processes; contractor or operator errors; and major incidents and/or catastrophic events such as fires, explosions, earthquakes or storms. As a result, there is a risk that the Company may not have the capacity to meet customer demand or to meet future demand when it arises. Failure to comply with health and safety

laws and regulations may result in additional costs for corrective measures, penalties or in restrictions on the Company's manufacturing operations.

Operating Risk and Insurance Coverage

The Company has directors and officers insurance to protect its assets, operations and employees. The Company's insurance is subject to coverage limits and exclusions and may not be available for the risks and hazards to which the Company is expected to be exposed. In addition, no assurance can be given that such insurance will be adequate to cover the Company's liabilities or will be generally available in the future, or if available, that premiums will be commercially justifiable. If the Company were to incur substantial liability and such damages were not covered by insurance or were in excess of policy limits, or if the Company were to incur such liability at a time when it is not able to obtain liability insurance, its business, results of operations and financial condition could be materially adversely affected.

Costs of Operating as Public Company

As a public company, the Company will incur significant legal, accounting and other expenses. As a public company, the Company is subject to various securities rules and regulations, which impose various requirements on the Company, including the requirement to establish and maintain effective disclosure and financial controls and corporate governance practices. The Company's management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase the Company's legal and financial compliance costs and make some activities more time-consuming and costly.

Management of Growth

The Company may be subject to growth-related risks, including capacity constraints and pressure on its internal systems and controls. The ability of the Company to manage growth effectively will require it to continue to implement and improve its operational and financial systems and to expand, train and manage its employee base. The inability of the Company to deal with this growth may have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

Conflicts of Interest

The Company may be subject to various potential conflicts of interest because of the fact that some of its officers and directors may be engaged in a range of business activities. The Company's executive officers and directors may devote time to their outside business interests, so long as such activities do not materially or adversely interfere with their duties to the Company. In some cases, the Company's executive officers and directors may have fiduciary obligations associated with these business interests that interfere with their ability to devote time to the Company's business and affairs and that could adversely affect the Company's operations. These outside business interests could require significant time and attention of the Company's executive officers and directors.

In addition, the Company may also become involved in other transactions which conflict with the interests of its directors and the officers who may from time-to-time deal with persons, firms, institutions or companies with which the Company may be dealing, or which may be seeking investments similar to those desired by it. The interests of these persons could conflict with those of the Company, and from time to time, these persons may be competing with the Company for available investment opportunities.

Conflicts of interest, if any, will be subject to the procedures and remedies provided under applicable laws. In particular, in the event that such a conflict of interest arises at a meeting of the Company's directors, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. In accordance with applicable laws, the Board is required to act honestly, in good faith and in the best interests of the Company.

Foreign Operations

In addition to operations carried out in Canada, the United States and the UK, the Company intends to carry out international operations through an office in Ireland. As a result, the Company may be subject to political, economic and other uncertainties, including, but not limited to, additional implications that may have a material impact on the Company's ability to operate in other jurisdictions including:

- differences in the regulatory requirements for drug approvals;
- differing requirements for securing, maintaining or obtaining freedom to operate;
- the potential for reduced protection for intellectual property rights;
- challenges with compliance to different regulations and court systems of multiple jurisdictions and
- compliance with a wide variety of foreign laws, treaties and regulations;
- differing reimbursement regimes and price controls in certain international markets;
- differing labor relations that create challenges with staffing and managing international operations; and
- impacts on manufacturing capabilities leading to production shortages.

The Company's international operations may also be adversely affected by laws and policies of Canada affecting foreign trade, taxation and investment. In the event of a dispute arising in connection with its foreign operations, the Company may be subject to the exclusive jurisdiction of foreign courts or may not be successful in subjecting foreign persons to the jurisdiction of courts in Canada or enforcing Canadian judgments in foreign jurisdictions.

Similarly, to the extent that the Company's assets are located outside of Canada, investors may have difficulty collecting from the Company any judgments obtained in the Canadian courts and predicated on the civil liability provisions of securities laws. Consequently, investors may be effectively prevented from pursuing remedies against the Company under Canadian securities laws or otherwise. The Company may also be hindered or prevented from enforcing its rights with respect to a governmental entity or instrumentality because of the doctrine of sovereign immunity.

Exchange Rate Fluctuations

Due to the international scope of the Company's current and future operations, the Company's assets, future earnings and cash flows may be influenced by movements in exchange rates of several currencies, particularly the British Pound, the United States dollar, Canadian Dollar and the Euro. The Company's reporting currency is denominated in United States dollars and the Company's functional currency is the United States dollar and the majority of the Company's operating expenses are paid in United States dollars. The Company may also regularly acquire services, consumables and materials in British Pounds, United States dollars, Canadian dollars and other currencies. Further, future revenue may be derived from abroad. As a result, the Company's business and the price of the Company's products may be affected by fluctuations in foreign exchange rates between the British Pound, the United States dollar, the Canadian dollar and other currencies, which may also have a significant impact on the Company's results of operations and cash flows from period to period. Currently, the Company does not have any exchange rate hedging arrangements in place.

Cybersecurity and Privacy Risk

The Company's information systems and any third-party service providers and vendors are vulnerable to an increasing threat of continually evolving cybersecurity risks. These risks may take the form of malware, computer viruses, cyber threats, extortion, employee error, malfeasance, system errors or other types of risks, and may occur from inside or outside of the respective organizations. Cybersecurity risk is increasingly difficult to identify and quantify and cannot be fully mitigated because of the rapidly evolving nature of the threats, targets and consequences. Attackers are increasingly using tools and techniques, including artificial intelligence, that are designed to circumvent controls, avoid detection and remove or obfuscate forensic evidence, and any integration of artificial intelligence into the Company's or its third parties' operations may pose new or unknown cybersecurity risks. Even with the implementation of security measures, the Company's information technology systems and those of third parties the Company interacts with are susceptible to risks that unauthorized parties may attempt to gain access to these systems through fraud or other means of deceiving third-party service providers, employees or vendors, attack, damage, or interruption from computer security incidents and cyberattacks such as malware (e.g. ransomware), phishing and other social engineering attacks employee or contractor theft, misuse or human error, denial or degradation of service attacks, supply chain attacks, advanced persistent threats from nation-state actors, attacks developed or enhanced using artificial intelligence, and unauthorized access or use (including unauthorized use of artificial intelligence) by persons inside or outside the Company's organization. The Company's operations depend, in part, on how well networks, equipment, IT systems and software are protected against damage from a number of threats. These operations also depend on the timely maintenance, upgrade and replacement of networks, equipment, IT systems and software, as well as pre-emptive expenses to mitigate the risks of failures. However, if the Company is unable or delayed in maintaining, upgrading or replacing IT systems and software, the risk of a cybersecurity incident could materially increase. Any of these and other events could result in information system failures, delays and/or increases in capital expenses. The loss of clinical trial data from completed, ongoing or planned clinical trials, including data held by the Company's CROs, could result in delays in the Company's regulatory approval efforts and significantly increase its costs to recover or reproduce the data. The failure of information systems or a component of information systems could,

depending on the nature of any such failure, adversely impact the Company's reputation and results of operations.

The Company may collect and store certain personal or health information about clinical trial participants and are responsible for protecting such information from privacy breaches. The Company is subject to evolving data protection laws in the jurisdictions in which it conducts clinical trials, including the EU General Data Protection Regulation and the UK General Data Protection Regulation, in addition to Canada and U.S. privacy laws. A privacy breach may occur through procedural or process failure, information technology malfunction, or deliberate unauthorized intrusions. In addition, theft of data is an ongoing risk whether perpetrated via employee collusion or negligence or through deliberate cyber-attack. Any such privacy breach or theft could have a material adverse effect on the Company's business, financial condition and results of operations.

In addition, there are a number of laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the privacy rules under the *Personal Information Protection and Electronic Documents Act* (Canada) ("**PIPEDA**") and where applicable, provincial legislation governing personal health information, protect medical records and other personal health information by limiting their use and disclosure of health information to the minimum level reasonably necessary to accomplish the intended purpose. If the Company were found to be in violation of the privacy or security rules under PIPEDA or other laws protecting the confidentiality of medical patients health information, the Company could be subject to sanctions and civil or criminal penalties, which could increase its liabilities, harm its reputation and have a material adverse effect on the Company's business, financial condition and results of operations.

Risks Related to Artificial Intelligence

The Company uses, and may further adopt, artificial intelligence ("**AI**") technologies to support research, development, data analysis, and operational activities. The use of AI involves risks, including potential errors, biases, or limitations in AI outputs and the underlying data sets, which could adversely affect research results, development decisions, or regulatory submissions. The regulatory framework governing AI, particularly in healthcare and life sciences, is evolving and may impose additional compliance requirements or restrict certain AI applications, increasing costs or delaying development. The Company may also rely on third-party AI tools, which may present risks related to data security, intellectual property rights, and service availability. Any failure to effectively manage these risks could have a material adverse effect on the Company's business and prospects.

Environmental Regulation and Risks

The Company's operations are subject to environmental regulations that mandate, among other things, the maintenance of air and water quality standards and land reclamation. They also set forth limitations on the generation, transportation, storage and disposal of solid and hazardous waste. Environmental legislation is evolving in a manner which could include stricter standards and enforcement, increased fines and penalties for non-compliance, more stringent environmental assessments of proposed projects and a heightened degree of responsibility for companies and their

officers, directors and employees. There is no assurance that future changes in environmental regulation, if any, will not adversely affect the Company's operations.

Failure to comply with applicable laws, regulations and permitting requirements may result in enforcement actions thereunder, including orders issued by regulatory or judicial authorities causing operations to cease or be curtailed, and may include corrective measures requiring capital expenditures, installation of additional equipment, or remedial actions. The Company may be required to compensate those suffering loss or damage by reason of its operations and may have civil or criminal fines or penalties imposed for violations of applicable laws or regulations.

Amendments to current laws, regulations and permits governing NSAs and related products, or more stringent implementation thereof, could have a material adverse impact on the Company and cause increases in expenses, capital expenditures or production costs or reduction in levels of production or require abandonment or delays in development.

Legalization of Scheduled Serotonergic Agonists

Despite the current status of many psychotropic substances as controlled substances in the United States and Canada (see "*Regulatory Framework"*), there may be changes in the status of some of these substances under the laws of certain jurisdictions. The legalization of scheduled serotonergic agonists with inadequate regulatory oversight may lead to the development of psychotropic tourism in such states in clinics without proper therapeutic infrastructure or adequate clinical research. The expansion of such an industry which could put patients at risk may bring reputational and regulatory risk to the entire serotonergic agonist industry, leading to challenges for the Company to achieve regulatory approval. The legalization of psychotropic compounds in the future may also impact commercial sales for the Company due to a reduced barrier to entry for serotonergic agonists leading to a risk of increasing competition.

Even if HLP003 or HLP004 receives FDA approval, neither can be commercially marketed in the United States until the DEA reschedules the relevant substance, or schedules the product itself, in Schedule II, III, IV or V. The DEA scheduling determination depends on FDA approval and the FDA's recommendation as to the appropriate schedule, and requires notice-and-comment rulemaking that is subject to public comment and requests for hearing. The scheduling process may take significantly longer than the 90-day period contemplated by the CSA, and the FDA or the DEA may require additional data regarding abuse or misuse potential, which could increase costs and delay launch. There can be no assurance that the DEA will make a favorable scheduling decision. Individual states would also need to schedule any approved product, which may occur automatically based on federal action or may require state rulemaking or legislative action, and adverse or delayed state scheduling could limit the commercial attractiveness of the Company's products. Following rescheduling, the manufacture, importation, distribution, storage, prescribing and dispensing of any approved product would continue to be subject to significant DEA and state regulation. Comparable rescheduling processes would be required in Canada, the UK, the EU and other jurisdictions.

Forward-Looking Statements May Prove to be Inaccurate

Investors should not place undue reliance on forward-looking statements. By their nature, forward-looking statements involve numerous assumptions, known and unknown risks and uncertainties, of both general and specific nature, that could cause actual results to differ materially from those suggested by the forward-looking statements or contribute to the possibility that predictions, forecasts or projections will prove to be materially inaccurate.

Effects of Inflation

Global markets have experienced increased rates of inflation. Inflation itself, as well as certain governmental efforts to combat inflation, may have significant negative effects on any economy which the Company does business. Past governmental efforts to curb inflation have involved certain drastic economic measures, which had a materially adverse impact on the level of economic activity in these countries. Any future economic measures to curb inflation could be expected to have similar adverse effects on the level of economic activity in the market which the Company does business and, in turn, on the operations of the Company, including by increasing the Company's research and development, clinical trial, manufacturing and personnel costs and adversely affecting conditions in the capital markets on which the Company depends to fund its operations.

Disruptions at the FDA and Other Regulatory Authorities Could Delay the Review of the Company's Regulatory Submissions

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including reductions in force or hiring freezes, government budget and funding levels, government shutdowns, the ability to hire and retain key personnel, and statutory, regulatory and policy changes. The current U.S. presidential administration has implemented policies directed towards reducing the headcount and costs of U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may affect the FDA's ability to conduct its activities. If these or other disruptions prevent or hinder the FDA or other regulatory authorities from conducting inspections, reviews or other activities, including providing the Company with timely advice on its development programs, the timing of the Company's regulatory submissions and any approvals of HLP003 or HLP004 could be delayed, which could have a material adverse effect on the Company's business and on its ability to access the capital markets.

Tariffs, Trade Restrictions and Drug Pricing Initiatives Could Adversely Affect the Company

The U.S. Department of Commerce has initiated national security investigations into the importation of pharmaceuticals and pharmaceutical ingredients under Section 232 of the Trade Expansion Act of 1962, and the U.S. administration has announced tariffs on branded or patented pharmaceuticals imported into the United States from manufacturers that are not building manufacturing facilities in the United States, as well as broader reciprocal tariffs that have prompted retaliatory measures by other countries. The U.S. administration has also sought to tie U.S. drug prices to lower prices paid in other countries through most-favored-nation pricing initiatives. In addition, the BIOSECURE Act, enacted in December 2025, restricts certain dealings with designated biotechnology companies of concern. The Company relies on third-party manufacturers, CROs and suppliers located in several

countries. These measures could increase the Company's costs, disrupt its supply chain, require it to change manufacturing partners or suppliers on less favorable terms, and, if any of its product candidates is approved, adversely affect pricing, reimbursement and patient access.

Political and Economic Conditions

Political and economic conditions directly affect the Company's business and can result in a material adverse effect on the Company. Macroeconomic policies imposed by foreign governments could have significant impact on the Company. As certain global markets experience increased inflation, certain government actions to control inflation may have significant impact on the Company.

The Company cannot control or predict foreign government implementation of changes to existing policies that may impact the Company's operations in foreign markets and, consequently, its business. The Company's business, operating results and financial condition and prospects, as well as the market price of its securities, may be adversely affected by changes in government public policies, whether federal, state or local, that affect, without limitation:

- inflation;
- fluctuations in exchange rates;
- exchange controls and restrictions on remittances abroad;
- interest rates and monetary policies;
- import and export controls;
- liquidity of domestic capital, credit and financial markets;
- expansion or contraction of foreign economies, as measured by rates of growth in gross domestic product;
- fiscal policies; and
- other political, social and economic developments in or affecting foreign markets.

Government policies and measures to combat inflation, along with public speculation about such policies and measures, have often had adverse effects on global economies, have contributed to economic uncertainty and may increase volatility in foreign securities markets. Government action to control inflation may involve actions such as price and salary controls, currency devaluations, capital limitations, limits on imports and other actions which could significantly impact the operations of the Company.

Other policies and measures adopted by governments, include interest rate adjustments, intervention in the currency markets or actions to adjust or fix the value of the local currency may adversely affect the target market's economy, the Company's business and results of operations.

Uncertainty over whether federal governments will implement reforms or changes in policy or regulation affecting these or other factors in the future may affect economic performance and contribute to economic uncertainty in markets that the Company operates or relies on, which may in turn have adverse effects on the Company's operations in the market and consequently on the results of its operations.

Litigation Risk

As of the date hereof, no material litigation or class proceedings have been commenced or certified. Should any litigation or class actions that the Company becomes involved in be unable to be resolved favorably or if any claims or litigation are determined against the Company, the Company's financial position, operating results and the trading price of the Common Shares could be materially adversely affected.

The Company faces the risk of various claims, legal proceedings, and class actions. Such actions could result in liabilities or necessitate operational changes, negatively impacting results. Even favorable resolutions can divert resources, generate substantial legal costs, and harm reputation.

The Company may be exposed to securities class action investigations or proceedings, especially following share price volatility or public disclosures. These proceedings could allege violations of securities laws or misrepresentations. Defending such claims are potentially costly and time-consuming and may lead to significant monetary judgments, settlements, or regulatory penalties. Any liability exceeding insurance coverage could materially and adversely affect the Company's business, financial condition, and results.

Application and Interpretation of Tax Laws

The Company is subject to direct and indirect taxes in various foreign jurisdictions. The amount of tax that the Company pays, directly or indirectly, is subject to the interpretation of applicable tax laws in the jurisdictions of operations in which the Company has interests. The Company has taken and will continue to take tax positions based on the application and interpretation of tax laws, but tax accounting often involves complex matters and judgment is required in determining the Company's foreign provisions for taxes and other tax liabilities. There can be no assurance that a taxing authority will not have a different interpretation of the law and assess the Company, or the operations in which the Company has interests, with additional taxes. Further, the Company's future effective tax rates could be impacted by changes in tax laws or regulations, and changing interpretation of existing laws or regulations. Both domestic and international tax laws, and interpretation of the tax laws, are subject to change as a result of changes in fiscal policy, changes in legislation, evolution of regulation and court rulings. The application of these tax laws and related regulations is subject to legal and factual interpretation, judgment and uncertainty.

Enforcement of Civil Liabilities

Certain of the Company's subsidiaries and assets are located outside of Canada. Accordingly, it may be difficult for investors to enforce within Canada any judgments obtained against the Company, including judgments predicated upon the civil liability provisions of applicable Canadian securities laws or otherwise. Consequently, investors may be effectively prevented from pursuing remedies against the Company under Canadian securities laws or otherwise.

The Company has subsidiaries incorporated in the United States and Ireland. It may not be possible for shareholders to effect service of process outside of Canada against the directors and officers of the Company who are not resident in Canada. In the event a judgment is obtained in a Canadian court

against one or more of such persons for violations of Canadian securities laws or otherwise, it may not be possible to enforce such judgment against persons not resident in Canada. Additionally, it may be difficult for an investor, or any other person or entity, to assert Canadian securities law or other claims in original actions instituted in the United States and Ireland. Courts in such jurisdictions may refuse to hear a claim based on a violation of Canadian securities laws or otherwise on the grounds that such jurisdiction is not the most appropriate forum to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the local law, and not Canadian law, is applicable to the claim. If Canadian law is found to be applicable, the content of applicable Canadian law must be proven as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by foreign law.

Pandemics, Epidemics and Other Health Risks

Pandemics, epidemics and other health risks could have an adverse effect on the Company's business. Pandemics, epidemics and other health risks could occur, which could adversely affect the Company's ability to conduct its operations as currently conducted, or the ability of suppliers to provide the Company with products and services needed to operate the business.

Pandemics, epidemics and other health risks could have an adverse effect on the economy and financial markets, resulting in a decline of commercial activity. Any of these events could have an adverse effect on the Company's business and financial performance.

Risks Related to Intellectual Property

Trademark Protection

Failure to register, maintain and properly use trademarks for the Company or its products could result in loss or limitation of trademark rights and could require the Company to rebrand its products, resulting in a material adverse impact on its business.

Trade Secrets, Confidential Information and Know-How Protection

The Company relies on third parties to develop its products and, as a result, must share trade secrets, confidential information and know-how with them. The Company seeks to protect its proprietary technology in part by entering into non-disclosure and confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with its collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements restrict the ability of the Company's collaborators, advisors, employees and consultants to publish data potentially relating to its trade secrets, confidential information and know-how without the Company's approval.. Its academic and clinical collaborators typically have rights to publish data, provided that the Company is notified in advance and may delay publication for a specified time in order to secure any intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by the Company, although in some cases the Company may share these rights with other parties. The Company may also conduct joint research and development programs which may require it to share trade secrets, confidential information and know-how under the terms of research and development

collaboration or similar agreements. Despite the Company's efforts to protect its trade secrets, confidential information and know-how, the Company's competitors may discover its trade secrets, confidential information and know-how, either through breach of these agreements, independent development or publication of information. A competitor's discovery of the Company's trade secrets, confidential information and know-how may impair its competitive position and could have a material adverse effect on its business and financial condition.

Patent Protection

The Company's commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for its current and future therapeutic candidates and associated therapies, digital therapies, methods used to manufacture the underlying therapeutic substances, and the methods for treating patients using those substances and therapies, or on licensing in such rights. Failure to obtain, maintain, protect, enforce or extend adequate patent and other intellectual property rights could materially adversely affect the Company's ability to develop and market its current and future therapeutic candidates and associated therapies, and could adversely affect the Company's operations and prospects.

The Company cannot be certain that patents will be issued or granted with respect to patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid or unenforceable. The patent position of companies like the Company is generally uncertain because it involves complex legal and factual considerations. The standards applied by the UK Intellectual Property Office, the European Patent Office, the USPTO, the Canadian Intellectual Property Office (the "**CIPO**") and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in pharmaceutical patents. Consequently, patents may not issue from the Company's pending patent applications, and even if they do issue, such patents may not issue in a form that effectively prevents others from developing or commercializing competing therapies. As such, the Company does not know the degree of future patent protection that it will have on its proprietary therapies.

The patent prosecution process is expensive, complex and time-consuming, and the Company, its current or future third-party partners, licensors, licensees, or collaboration partners may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that the Company or its licensors, licensees or collaboration partners will fail to identify patentable aspects of inventions made in the course of research, development or commercialization activities before it is too late to pursue patent protection on them. In addition, although the Company enters into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of its R&D output, such as its employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing the Company's ability to seek patent protection. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the UK, the US, Canada and other jurisdictions are typically not published until 18 months after filing, or in some cases not published until and unless granted. Therefore, the Company cannot be certain that it is the first to make the inventions claimed in its

patents or pending patent applications, or that it was the first to file for patent protection of such inventions. Similarly, the Company cannot be certain that for any licensed patents or pending patent applications, the named inventor(s) or applicant(s) were the first to make the inventions claimed in such patents or pending patent applications or that the named applicant(s) were the first to file for patent protection for such inventions.

Further, the issuance, scope, validity, enforceability and commercial value of the Company's and its current or future licensors', licensees' or collaboration partners' patent rights are highly uncertain. The Company and any potential licensors' pending and future patent applications may not result in patents being issued that protect the Company's therapies, in whole or in part, or that effectively prevent others from commercializing competitive technologies and therapies.

Moreover, in some circumstances, the Company may not have the right to control the preparation, filing and prosecution of patent applications, or the maintenance of resulting patents, where the Company licenses technology from or to third parties. In such circumstances, the Company may be reliant on its licensors, licensees or collaboration partners to prosecute and maintain such patent rights. If the Company engages with licensors, licensees or collaboration partners and they fail to establish, maintain or protect such patent or other intellectual property rights, such rights may be lost, narrowed or impaired. If such licensors, licensees or collaboration partners were not fully cooperative or disagree with the Company as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent examination process may require the Company or its licensors, licensees or collaboration partners to narrow the scope of the claims in pending and future patent applications, which may result in more limited patent protection than originally filed. The validity and scope of patent rights may be affected by prior art that is unknown or unavailable to the Company at the time a patent application is filed or prosecuted. The Company cannot guarantee that all potentially relevant prior art relating to its patents and patent applications has been identified. If such prior art exists, it could invalidate or narrow the scope of a patent or prevent a patent from issuing from a pending patent application. Accordingly, the Company cannot guarantee that its patent applications will result in patents being granted with claims of the scope sought or at all, or that any patents that are granted will remain valid and enforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and the Company's patents may be challenged in the courts or patent offices in the UK and abroad. Even if patents do successfully issue and even if such patents cover the Company's current and future therapeutic candidates, third parties may initiate an opposition, interference, re-examination, post-grant review, inter partes review, impeachment, nullification or derivation proceedings in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated.

Patent applications filed by or on behalf of the Company or its licensors, licensees or collaboration partners cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. In addition, patents and other intellectual property rights will not protect the Company's current and any future therapeutic candidates if third parties, including the

Company's competitors, design around the Company's protected technology and its current and any future therapeutic candidates without infringing, misappropriating or otherwise violating the Company's patents or other intellectual property rights. Moreover, some of the Company's patents and patent applications may be co-owned with third parties in the future. If the Company is unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including the Company's competitors, and the Company's competitors could market competing therapies and technology. In addition, the Company may need the cooperation of any such co-owners of its patents in order to enforce such patents against third parties, and such cooperation may not be provided. Any of the foregoing could have a material adverse effect on the Company's competitive position, business, financial conditions, results of operations, and prospects.

As described above, patent applications are confidential for a period of time after filing in many jurisdictions, and until issued in certain jurisdictions. Accordingly, the Company cannot be certain that the Company or its current or future licensors, licensees or collaborators were or will be the first to file any patent application related to a therapeutic candidate. Even where the Company has a valid and enforceable patent, it may not be able to exclude others from practicing the Company's invention where the other party can show that they used the invention in commerce before the Company's filing date or the other party benefits from a compulsory license. In addition, the Company may be subject to third party challenges regarding the Company's exclusive ownership of the Company's intellectual property. If a third party were successful in challenging the Company's exclusive ownership of any of the Company's intellectual property, the Company may lose its right to use such intellectual property, such third party may be able to license such intellectual property to other third parties, including the Company's competitors, and the Company's competitors could market competing therapies and technology. Any of the foregoing could have a material adverse effect on the Company's competitive position, business, financial conditions, results of operations, and prospects.

As is the case with other biotechnology and pharmaceutical companies, the Company's success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the breakthrough neuropsychiatry industry is a technologically and legally complex process, and obtaining and enforcing breakthrough neuropsychiatry patents is costly, time consuming and inherently uncertain. Patent reform could increase the uncertainties and costs surrounding the prosecution of the Company's and its licensors' or collaborators' patent applications and the enforcement or defense of the Company or its licensors' or collaborators' issued patents.

Patent Litigation

The Company has filed a number of provisional patent applications but even if regular patent applications are filed claiming priority to one or more of the provisional patent applications, there can be no assurance that any or all of these patent applications will issue into a valid patent. Such failure to issue could have a material adverse effect on the Company. In the event that a patent issued to the Company is challenged, one or more of the Company's patents could be invalidated or limited in scope. The Company could also become involved in interference, impeachment, or other proceedings

relating to its patents or patent applications, including proceedings concerning patent validity, ownership, entitlement or priority.

Patent litigation is widespread in the pharmaceutical industry and the Company cannot predict how this will affect its efforts to form strategic alliances, conduct clinical testing, or manufacture and market any of its therapeutic candidates and associated therapies that it may successfully develop. If the Company becomes involved in any litigation, interference, impeachment or other administrative proceedings, it will likely incur substantial expenses and the efforts of its technical and management personnel will be significantly diverted. The Company cannot make any assurances that it will have the financial or other resources necessary to enforce or defend a patent infringement or proprietary rights violation action. Moreover, if the Company's therapeutic candidates and associated therapies infringe patents, trademarks or proprietary rights of others, it could, in certain circumstances, become liable for substantial damages, which also could have a material adverse effect on the business of the Company, its financial condition and results of operation.

Patent litigation is less likely during product development as many jurisdictions contain exemptions from patent infringement for the purpose of obtaining regulatory approval of a product. Where patent rights are shared, whether through co-ownership or licences granting rights in different "fields of use", the actions or omissions of one owner or licensee could adversely affect the rights of other owners or licensees and, in certain circumstances, could lead to the invalidity of the applicable patent. If the Company is unable to avoid infringing the patent rights of others, the Company may be required to seek a licence, defend an infringement action or challenge the validity of a third party patent in court. Such results could have a material adverse effect on the business of the Company, its financial condition and results of operation. Regardless of the outcome, patent litigation is costly and time consuming. In some cases, the Company may not have sufficient resources to bring these actions to a successful conclusion, and, even if the Company is successful in these proceedings, it may incur substantial costs and divert technical and management time and attention in pursuing these proceedings, which could have a material adverse effect on the business of the Company, its financial condition and results of operation.

Any infringement or misappropriation of the Company's intellectual property could damage the Company's value and limit its ability to compete. The Company's ability to enforce and protect its intellectual property rights may be limited in certain countries outside the U.S., which could make it less burdensome for competitors to capture market position in such countries by utilizing technologies that are similar to those developed or licensed by the Company. Competitors may also harm the Company's sales by designing products that mirror the capabilities of the Company's products or technology without infringing on its intellectual property rights. If the Company does not obtain sufficient protection for its intellectual property, or if it is unable to effectively enforce its intellectual property rights, its competitiveness could be impaired, which would limit its growth and future revenue. The Company may also find it necessary to bring infringement or other actions against third parties to enforce and protect its intellectual property rights. As described above, litigation of this nature, even if successful, is expensive and time consuming to pursue. There can be no assurance that the Company will have the financial or other resources to defend or enforce its rights or prevent other parties from developing similar technology or designing around its intellectual property.

The Company is not aware of any infringement by the Company of the intellectual property rights of any third party. In the event that products sold by the Company are deemed to infringe upon the patents or proprietary rights of others, the Company could be required to modify its products or obtain a licence for the manufacture and/or sale of such products or cease selling such products. In such event, there can be no assurance that the Company would be able to do so in a timely manner, upon acceptable terms and conditions, or at all, and the failure to do any of the foregoing could have a material adverse effect upon the Company's business and its financial condition. If the Company's products or proposed products are deemed to infringe or likely to infringe upon the patents or proprietary rights of others, the Company could be subject to injunctive relief and, under certain circumstances, become liable for damages, which could also have a material adverse effect on the Company's business, its financial condition and results of operation.

Protection of Intellectual Property

The Company will be able to protect its intellectual property from unauthorized use by third parties only to the extent that the Company's proprietary technologies, key products and any future products are covered by valid and enforceable intellectual property rights including patents, are effectively maintained as trade secrets and provided the Company has the funds to enforce its rights, if necessary.

To protect the Company's competitive position, the Company may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to the Company from time to time, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. As described above, defense and enforcement of intellectual property rights is difficult, unpredictable and expensive. Many parties adverse to the Company, its licensors or its collaboration partners in these proceedings may have substantially greater resources to devote to such legal actions than the Company or its licensors or collaboration partners. Accordingly, despite the efforts of the Company or its licensors or collaboration partners, the Company or its licensors or collaboration partners may not prevent third parties from infringing upon, misappropriating or otherwise violating intellectual property rights. The Company may be unable to adequately protect or enforce the intellectual property rights that it owns or controls in certain jurisdictions, particularly in countries where intellectual property rights may not be protected to the same extent as in the UK, EU, the US and Canada. The Company may fail to successfully enforce its rights, in which case the Company's competitors and other third parties may use, develop or commercialize the Company's therapies without payment to the Company.

In addition, litigation involving the Company's licensed patents carries the risk that one or more of the Company's licensed patents will be invalidated or limited in scope (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to exploit the Company's licensed patents, commercialize the Company's therapies, and compete directly with the Company, without payment to the Company.

If the Company initiates legal proceedings against a third party to enforce a patent covering one of its investigational therapies, the defendant may counterclaim that the patent is invalid or unenforceable. In patent litigation in the UK, EU, the US or Canada, defendant counterclaims alleging invalidity or unenforceability are commonplace. A validity challenge may be based on failure to satisfy one or more statutory requirements, including, for example, novelty, non-obviousness or enablement

requirements. A claim that a patent is unenforceable may be based on an allegation that a person involved with prosecution of the patent withheld material information from the UK Intellectual Property Office, European Patent Office, the USPTO, the CIPO, or made material misrepresentations during prosecution. Third parties may also raise challenges to the validity of the Company's patent claims before administrative bodies in the US or abroad, even outside the context of litigation, such as re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (i.e., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to the Company's patents in such a way that they no longer cover the Company's current or any future therapeutic candidates. The outcome following legal challenges of invalidity and unenforceability during patent litigation or other proceedings is unpredictable. With respect to a validity challenge, for example, the Company cannot be certain that there is no invalidating prior art, of which the Company and the patent examiner were unaware during prosecution. If a defendant or third party were to prevail on a legal assertion of invalidity or unenforceability, the Company would lose, at least part and perhaps all, the patent protection on the Company's current or one or more of any future therapeutic candidates. Such a loss of patent protection could have a material adverse impact on the Company's business financial condition, results of operations, and prospects. Further, litigation could result in substantial costs and diversion of technical and management resources, regardless of the outcome, and this could harm the Company's business and financial results.

Third-Party Licenses

A substantial number of patents have already been issued to other biotechnology and pharmaceutical companies. To the extent that valid third party patent rights cover the Company's products or services, the Company or its strategic collaborators would be required to seek licences from the holders of these patents in order to manufacture, use or sell these products and services. The required payments under such licenses would reduce the Company's profits from these products and services. The Company is currently unable to predict the extent to which it may wish or be required to acquire rights under such patents, the availability and cost of acquiring such rights and whether a licence to such patents will be available on acceptable terms or at all. There may be patents in the U.S. or in foreign countries or patents that will issue in the future that are unavailable to licence on acceptable terms. The Company's inability to obtain such licences may hinder or eliminate its ability to manufacture and market its products.

Further, if the Company obtains third party licences but fails to satisfy its obligation under those licences, including payment of annual maintenance fees, achievement of development and sales milestones, or fails to use commercially reasonable efforts to commercialize licensed products, the Company could lose its rights under such licences. Any such loss could have a material adverse effect on the Company's business and financial condition.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the UK Intellectual Property Office, the European Patent Office, the USPTO, the CIPO and foreign patent agencies in several stages over the lifetime of the patent. The European Patent Office, the USPTO, the CIPO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payments and other similar provisions during the patent application process. In certain circumstances, the Company may rely on its collaboration partners to pay applicable fees to

the US and comparable foreign patent offices and to take the necessary actions to maintain and protect the Company's intellectual property rights in accordance with applicable requirements. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If the Company, its licensors or collaboration partners fail to maintain the patents and patent applications covering the Company's investigational therapies, third parties, including its competitors may be able to enter the market with similar or identical therapies or technologies, which would have a material adverse effect on the Company's business, financial condition, results of operations, and prospects.

Financial and Accounting Risks

Substantial Number of Authorized but Unissued Common Shares

The Company has an unlimited number of Common Shares that may be issued by the Board without further action or approval of the Shareholders. While the Board will be required to fulfill its fiduciary obligations in connection with the issuance of such Common Shares, the Common Shares may be issued in transactions with which not all of the shareholders of the Company agree, and the issuance of such Common Shares will cause dilution to the ownership interests of the shareholders of the Company.

Dilution

The Company may issue additional Common Shares in subsequent offerings (including through the sale of securities convertible into or exchangeable for Common Shares) and upon the exercise of stock options or other securities exercisable for Common Shares. The Company cannot predict the size of any additional future issuances of Common Shares or the effect that future issuances and sales of Common Shares will have on the market price of the Common Shares. Issuances of a substantial number of additional Common Shares, or the perception that such issuances could occur, may adversely affect prevailing market prices for the Common Shares. With any additional issuance of Common Shares, investors will suffer dilution to their voting power and the Company may experience dilution in its earnings per share, including as a result of issuances under Helus Pharma's equity incentive plan, convertible or exchangeable securities, or other corporate arrangements, including the Rights Plan.

Negative Cash Flow from Operating Activities

The Company has had negative cash flow from operating activities since inception. Drug development involves long lead times, is very expensive and involves many uncertain variables. As such, significant capital investment will be required to achieve the Company's existing plans. The Company's net losses have had and will continue to have an adverse effect on, among other things, shareholder equity, total assets and working capital. The Company expects that losses may fluctuate from quarter to quarter and year to year, and that such fluctuations may be substantial based on the

stage of development of its principal programs. The Company cannot predict when it will become profitable, if at all. Accordingly, the Company will be required to obtain additional financing in order to meet its future cash commitments.

Additional Capital Requirements

As a research and development company, the Company expects to spend substantial funds to continue the research, development and testing of its prescription drug product candidates and to prepare to commercialize products subject to applicable regulatory approval. Substantial additional financing will be required if the Company is to be successful in continuing to develop its business and its products. No assurances can be given that the Company will be able to raise the additional capital that it will require for its anticipated future development. Any additional equity financing may be dilutive to investors and debt financing, if available, may involve restrictions on financing and operating activities. There is no assurance that additional financing will be available on terms acceptable to the Company, if at all. If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations or anticipated expansion. The Company's ability to successfully raise additional capital and maintain liquidity may be impaired by factors outside of its control, such as a shift in consumer attitudes towards certain therapeutic methods or a downturn in the economy.

Heightened regulatory scrutiny could also have a negative impact on the Company's ability to raise capital. The Company's business activities rely on developing laws and regulations in multiple jurisdictions. It is impossible to determine the extent of the impact of any new laws, regulations or initiatives that may be proposed, or whether any proposals will become law. The regulatory uncertainty surrounding the Company's current or any future products may adversely affect the Company's business and operations, including without limitation, the Company's ability to raise additional capital.

In addition, the Company may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving its business objectives. The Company will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. The Company may not be successful in such a transition.

Lack of Significant Product Revenue

To date, the Company has generated little product revenue and cannot predict when and if it will generate significant product revenue. The Company's ability to generate significant product revenue and ultimately become profitable depends upon its ability, alone or with partners, to successfully develop its prescription drug product candidates, obtain regulatory approval and commercialize products, including any of its current prescription drug product candidates or other prescription drug product candidates that it may develop, in-license or acquire in the future. The Company does not anticipate generating revenue from the sale of products for the foreseeable future. The Company expects its research and development expenses to increase in connection with its ongoing activities, particularly as it advances its prescription drug product candidates through clinical trials.

Estimates or Judgments Relating to Critical Accounting Policies

The preparation of Financial Statements in conformity with the International Financial Reporting Standards requires management to make estimates and assumptions that affect the amounts reported in the Financial Statements and accompanying notes. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, as provided in the notes to the Financial Statements, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. The Company's operating results may be adversely affected if the assumptions change or if actual circumstances differ from those in the assumptions, which could cause its operating results to fall below the expectations of securities analysts and investors, resulting in a decline in the share price of the Company. Significant assumptions and estimates used in preparing the Financial Statements include those related to income tax credits receivable, share based payments, impairment of non-financial assets, as well as cost recognition.

Inadequate Internal Controls

If the Company fails to maintain an effective system of internal controls, the Company might not be able to report its financial results accurately or prevent misstatement; and in that case, the Company's shareholders could lose confidence in its financial reporting, which would harm its business and could negatively impact the value of its shares. There can be no assurance that the Company will always successfully detect misstatements or implement necessary improvements in a timely fashion.

Risks Related to the Common Shares

Market for the Common Shares

There can be no assurance that an active trading market for the Common Shares will develop or, if developed, that any market will be sustained. The Company cannot predict the prices at which the Common Shares will trade. Fluctuations in the market price of the Common Shares could cause an investor to lose all or part of its investment in Common Shares. Factors that could cause fluctuations in the trading price of the Common Shares include: (i) announcements of new offerings, products, services or technologies; commercial relationships, acquisitions or other events by the Company or its competitors; (ii) price and volume fluctuations in the overall stock market from time to time; (iii) significant volatility in the market price and trading volume of companies commercializing serotonergic agonist pharmaceuticals; (iv) fluctuations in the trading volume of the Common Shares or the size of the Company's public float; (v) actual or anticipated changes or fluctuations in the Company's results of operations; (vi) whether the Company's results of operations meet the expectations of securities analysts or investors; (vii) actual or anticipated changes in the expectations of investors or securities analysts; (viii) litigation involving the Company, and/or the Company's peers with its industry; (ix) regulatory developments; (x) general economic conditions and trends; (xi) major catastrophic events; (xii) escrow releases and/or sales of large blocks of the Common Shares; (xiii) departures of key employees or members of management; or (xiv) an adverse impact on the Company from any of the other risks cited herein.

Significant Sales of the Common Shares

Although Common Shares held by existing shareholders of the Company will be freely tradable under applicable securities legislation, the Common Shares held by the Company's directors, executive officers, Control persons and certain other security holders may be subject to contractual lock-up restrictions and may also be subject to escrow restrictions pursuant to the policies of Cboe Canada. Sales of a substantial number of the Common Shares in the public market after the expiry of lock-up or escrow restrictions, or the perception that these sales could occur, could adversely affect the market price of the Common Shares and may make it more difficult for investors to sell Common Shares at a favorable time and price.

Volatile Market Price for the Common Shares

The securities markets in Canada have experienced high levels of price and volume volatility, and the market prices of securities of many companies have experienced wide fluctuations in price which have not necessarily been related to the operating performance, underlying asset values or prospects of such companies. There can be no assurance that continual fluctuations in price will not occur. The market, if any, for the Common Shares will be subject to such general market trends, notwithstanding the particular impact of these trends (or lack thereof) on the Company. The value of the Common Shares will be affected by such volatility.

The volatility of the Common Shares may affect the ability of holders to sell the Common Shares at an advantageous price or at all. Market price fluctuations in the Common Shares may be adversely affected by a variety of factors relating to the Company's business, including fluctuations in the Company's operating and financial results, such results failing to meet the expectations of securities analysts or investors and downward revisions in securities analysts' estimates in connection therewith, sales of additional Common Shares, governmental regulatory action, adverse change in general market conditions or economic trends, changes in interest rates or foreign exchange rates, acquisitions, dispositions or other material public announcements by the Company or its competitors, along with a variety of additional factors, including, without limitation, those set forth under the heading "Forward-Looking Statements" and these "Risk Factors." In addition, the market price for securities on stock markets, including Cboe Canada and Nasdaq, is subject to significant price and trading fluctuations. These fluctuations have resulted in volatility in the market prices of securities that often has been unrelated or disproportionate to changes in operating performance. These broad market fluctuations have in past, and may in the future continue to materially adversely affect the market price of the Company.

The Company Expects to Be a "Passive Foreign Investment Company"

Based on current business plans and financial expectations, the Company expects to be classified as a "passive foreign investment company" (a "**PFIC**") within the meaning of Section 1297(a) of the U.S. Internal Revenue Code of 1986, as amended (the "**Code**") for its current tax year and may be classified as a PFIC in future tax years. PFIC status is determined annually and depends on facts that may change. If the Company is a PFIC for any taxable year during which a U.S. holder holds Common Shares, the U.S. holder may be subject to adverse U.S. federal income tax consequences, including the treatment of gains and certain distributions as ordinary income, interest charges and

additional reporting requirements, unless the U.S. holder makes a timely qualified electing fund or mark-to-market election. U.S. holders should consult their own tax advisor regarding the tax consequences of the PFIC rules.

Tax Issues

There may be income tax consequences in relation to the Common Shares, which will vary according to circumstances. Independent advice from tax and legal advisers should be obtained.

No Dividends

The Company's current policy is, and will be, to retain earnings to finance the development and enhancement of its products and to otherwise reinvest in the Company. Therefore, the Company does not anticipate paying cash dividends on the Common Shares in the foreseeable future. The Company's dividend policy will be reviewed from time to time by the Board in the context of its earnings, financial condition and other relevant factors. Until the time that the Company does pay dividends, which it might never do, its shareholders will not be able to receive a return on their Common Shares unless they sell them.

ADDITIONAL INFORMATION

Additional information on the Company has been filed electronically through SEDAR+ and is available online at *www.sedarplus.ca*.

Approval

The Board has approved the disclosure in this MD&A.